Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request: cder_mpl1r_wp159, Report 1 of 2

Request ID: cder_mpl1r_wp159_nsdp_v01

Request Description: We assessed the use patterns of ranitidine and a comparator agent, famotidine, within the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1

Data Source: We distributed this request to 16 Sentinel Data Partners on October 28, 2019.

Report 1 of 2: This report includes data only from the Centers for Medicare and Medicaid Services (CMS) Data Partner, representing patients with Medicare fee-for-service coverage. The study period included data from January 1, 2010 through December 31, 2018. Please see Appendix A for the dates of available data. See Report 2 for results from all other Data Partners.

Study Design: We identified individuals with incident and prevalent use of ranitidine and famotidine, and then characterized use and dispensing patterns by examining all episodes of use occurring after the initial exposure (index). This is a Type 5 analysis described in the Query Request Package (QRP) documentation.

Exposures of Interest: We defined the exposures of interest, ranitidine and famotidine, using outpatient dispensing data and National Drug Codes (NDCs). We applied a washout period to identify the first valid exposure episode of incident drug use; otherwise we assessed all valid exposure episodes during the query period. Please see Appendix B for a list of generic and brand drug names, and Appendix C for a list of Healthcare Common Procedure Coding System (HCPCS) codes used to define exposures and incidence criteria in this request.

Cohort Eligibility Criteria: We did not require any pre-treatment health plan enrollment for the prevalent cohorts. For incident cohorts, we required members to be continuously enrolled in health plans with medical and drug coverage in the 183 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. Additionally, for the incident cohorts, we defined new use as no evidence of treatment with ranitidine, famotidine, cimetidine or nizatidine in the 183 days prior to their index date. The following age groups were included in the cohort: <2, 2-11, 12-17, 18-39, 40-64, and 65+ years. We formed the following six cohort groups for each of the two exposures of interest:

1. Prevalent cohorts with drug exposures administered in the form of oral solid or oral liquid;
2. Prevalent cohorts with drug exposures administered in the form of injection or intravenous;
3. Prevalent cohorts with drug exposures administered in the form of oral solid, oral liquid, injection or intravenous;
4. Incident cohorts with drug exposures administered in the form of oral solid or oral liquid;
5. Incident cohorts with drug exposures administered in the form of injection or intravenous;
6. Incident cohorts with drug exposures administered in the form of oral solid, oral liquid, injection or intravenous.

Baseline Characteristics: We characterized the following information on the index dispensing date: age, year, sex, whether the index drug was over-the-counter (OTC), and manufacturer of the index drug. In addition, we evaluated proton-pump inhibitor (PPI) use from the day after index until the end of follow-up. We identified PPI and all index drug use by NDCs and HCPCS codes. Please see Appendices D and E for a list of codes used to define baseline characteristics in this request.

Please see Appendices F and G for the specifications of parameters used in this request.

Limitations: Algorithms to define exposures, incidence criteria and baseline characteristics are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (https://dev.sentinelsystem.org/projects/sentinel/repos/sentinel-routine-querying-tool-documentation/browse).

Sentinel

Table of Contents

Sentinel

Table of Contents

Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1a. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	3,756,007	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	68.5	14.3
Age (years)	**Number**	**Percent**
<2	164	0.0%
2-11	524	0.0%
12-17	494	0.0%
18-39	176,525	4.7%
40-64	918,487	24.5%
65+	2,659,813	70.8%
Sex	**Number**	**Percent**
Female	*****	65.3%
Male	*****	34.7%
Other	*****	0.0%
Year	**Number**	**Percent**
2010	803,549	21.4%
2011	347,277	9.2%
2012	322,503	8.6%
2013	363,229	9.7%
2014	333,311	8.9%
2015	331,186	8.8%
2016	422,064	11.2%
2017	417,710	11.1%
2018	415,178	11.1%
Recorded Dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	87	0.0%
PPI use, post-index (day 1 to the end of follow-up)	2,121,181	56.5%
Index Date Dispensing by Manufacturer (Ranitidine Only):	**Number**	**Percent**
All Others	807,590	21.5%
Ahp	1,843	0.0%
Amneal Pharmace	1,392,148	37.1%
Apotex Corp	34,814	0.9%
Bedford Labs	*****	0.0%
Boehringer Cons	*****	0.0%
Boehringer/Chat	31	0.0%
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	*****	0.0%
Covis/Teligent	0	0.0%
Dr.Reddy'S Lab	68,072	1.8%
Glaxo Pharm	0	0.0%
Glaxosmithkline	1,800	0.0%
Glenmark Pharma	781,590	20.8%
Gsms, Inc.	90	0.0%
Hi-Tech/Akorn C	3,108	0.1%
Major Pharmaceu	3,415	0.1%
Mylan	*****	0.0%

Table 1a. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Index Date Dispensing by Manufacturer (Ranitidine Only):	Number	Percent
Mylan Instituti	3,177	0.1%
Par Pharm.	87,882	2.3%
Pfizer Cons.Hlt	0	0.0%
Pharmaceutical	9,639	0.3%
Precision Dose	12	0.0%
Ranbaxy Pharmac	16	0.0%
Sandoz	260,108	6.9%
Silarx/Lannett	4,746	0.1%
Strides Pharma	0	0.0%
Teligent Pharma	0	0.0%
Teva Usa	611,739	16.3%
Watson Labs	28	0.0%
Wockhardt Usa L	*****	0.0%
Zydus Pharmaceu	*****	0.0%

[1]All metrics based on total number of unique patients.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1b. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	264,585	
Demographics	**Number**	**Standard Deviation**
Mean Age (years)	68.7	12.2
Age (years)	**Number**	**Percent**
<2	0	0.0%
2-11	*****	*****
12-17	*****	*****
18-39	9,344	3.5%
40-64	55,163	20.8%
65+	200,054	75.6%
Sex	**Number**	**Percent**
Female	163,581	61.8%
Male	101,004	38.2%
Other	0	0.0%
Year	**Number**	**Percent**
2010	38,252	14.5%
2011	43,749	16.5%
2012	28,120	10.6%
2013	31,092	11.8%
2014	37,833	14.3%
2015	33,665	12.7%
2016	29,110	11.0%
2017	9,158	3.5%
2018	13,606	5.1%
Recorded Dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	0	0.0%
PPI use, post-index (day 1 to the end of follow-up)	146,240	55.3%
Index Date Dispensing by Manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	957	0.4%
Ahp	*****	0.0%
Amneal Pharmace	1,217	0.5%
Apotex Corp	28	0.0%
Bedford Labs	241	0.1%
Boehringer Cons	0	0.0%
Boehringer/Chat	0	0.0%
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	239	0.1%
Covis/Teligent	13	0.0%
Dr.Reddy'S Lab	22	0.0%
Glaxo Pharm	0	0.0%
Glaxosmithkline	0	0.0%
Glenmark Pharma	821	0.3%
Gsms, Inc.	0	0.0%
Hi-Tech/Akorn C	*****	0.0%
Major Pharmaceu	*****	0.0%
Mylan	0	0.0%

Table 1b. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Index Date Dispensing by Manufacturer (Ranitidine only):	Number	Percent
Mylan Instituti	*****	0.0%
Par Pharm.	48	0.0%
Pfizer Cons.Hlt	0	0.0%
Pharmaceutical	*****	0.0%
Precision Dose	0	0.0%
Ranbaxy Pharmac	0	0.0%
Sandoz	204	0.1%
Silarx/Lannett	*****	0.0%
Strides Pharma	0	0.0%
Teligent Pharma	*****	0.0%
Teva Usa	804	0.3%
Watson Labs	0	0.0%
Wockhardt Usa L	0	0.0%
Zydus Pharmaceu	442	0.2%

[1]All metrics based on total number of unique patients

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Table 1c. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	3,968,029	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	68.5	14.1
Age (years)	**Number**	**Percent**
<2	164	0.0%
2-11	529	0.0%
12-17	503	0.0%
18-39	182,850	4.6%
40-64	958,508	24.2%
65+	2,825,475	71.2%
Sex	**Number**	**Percent**
Female	*****	65.0%
Male	*****	35.0%
Other	*****	0.0%
Year	**Number**	**Percent**
2010	837,658	21.1%
2011	384,675	9.7%
2012	345,601	8.7%
2013	388,663	9.8%
2014	364,190	9.2%
2015	357,634	9.0%
2016	443,480	11.2%
2017	422,462	10.6%
2018	423,666	10.7%
Recorded Dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	86	0.0%
PPI use, post-index (day 1 to the end of follow-up)	2,233,709	56.3%
Index Date Dispensing by Manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	802,916	20.2%
Ahp	1,833	0.0%
Amneal Pharmace	1,382,934	34.9%
Apotex Corp	34,712	0.9%
Bedford Labs	211	0.0%
Boehringer Cons	*****	0.0%
Boehringer/Chat	31	0.0%
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	195	0.0%
Covis/Teligent	*****	0.0%
Dr.Reddy'S Lab	67,742	1.7%
Glaxo Pharm	0	0.0%
Glaxosmithkline	1,795	0.0%
Glenmark Pharma	776,195	19.6%
Gsms, Inc.	90	0.0%
Hi-Tech/Akorn C	3,061	0.1%
Major Pharmaceu	3,403	0.1%
Mylan	*****	0.0%

Table 1c. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Index Date Dispensing by Manufacturer (Ranitidine only):	Number	Percent
Mylan Instituti	3,171	0.1%
Par Pharm.	87,708	2.2%
Pfizer Cons.Hlt	0	0.0%
Pharmaceutical	9,547	0.2%
Precision Dose	12	0.0%
Ranbaxy Pharmac	16	0.0%
Sandoz	258,617	6.5%
Silarx/Lannett	4,684	0.1%
Strides Pharma	0	0.0%
Teligent Pharma	*****	0.0%
Teva Usa	608,327	15.3%
Watson Labs	28	0.0%
Wockhardt Usa L	*****	0.0%
Zydus Pharmaceu	359	0.0%

[1]All metrics based on total number of unique patients

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Table 1d. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	2,612,985	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	70.1	14.5
Age (years)	**Number**	**Percent**
<2	35	0.0%
2-11	206	0.0%
12-17	408	0.0%
18-39	113,915	4.4%
40-64	577,675	22.1%
65+	1,920,746	73.5%
Sex	**Number**	**Percent**
Female	1,649,147	63.1%
Male	963,838	36.9%
Other	0	0.0%
Year	**Number**	**Percent**
2010	439,855	16.8%
2011	245,124	9.4%
2012	234,945	9.0%
2013	265,076	10.1%
2014	248,227	9.5%
2015	259,174	9.9%
2016	313,335	12.0%
2017	310,720	11.9%
2018	296,529	11.3%
Recorded Dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	50	0.0%
PPI use, post-index (day 1 to the end of follow-up)	1,261,674	48.3%

[1]All metrics based on total number of unique patients

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Table 1e. Aggregated Baseline Table for Famotidine, Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	22,694	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	67.0	14.4
Age (years)	**Number**	**Percent**
<2	0	0.0%
2-11	*****	*****
12-17	*****	*****
18-39	1,501	6.6%
40-64	5,554	24.5%
65+	15,637	68.9%
Sex	**Number**	**Percent**
Female	14,671	64.6%
Male	8,023	35.4%
Other	0	0.0%
Year	**Number**	**Percent**
2010	2,675	11.8%
2011	2,643	11.6%
2012	2,817	12.4%
2013	2,572	11.3%
2014	2,216	9.8%
2015	2,359	10.4%
2016	2,277	10.0%
2017	2,293	10.1%
2018	2,842	12.5%
Recorded Dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	0	0.0%
PPI use, post-index (day 1 to the end of follow-up)	13,082	57.6%

[1]All metrics based on total number of unique patients

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Table 1f. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid or Injection/Intravenous (0-day washout, 0-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	2,630,636	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	70.1	14.5
Age (years)	**Number**	**Percent**
<2	35	0.0%
2-11	206	0.0%
12-17	409	0.0%
18-39	114,935	4.4%
40-64	581,771	22.1%
65+	1,933,280	73.5%
Sex	**Number**	**Percent**
Female	1,660,390	63.1%
Male	970,246	36.9%
Other	0	0.0%
Year	**Number**	**Percent**
2010	442,209	16.8%
2011	247,282	9.4%
2012	237,279	9.0%
2013	267,064	10.2%
2014	249,975	9.5%
2015	260,892	9.9%
2016	314,972	12.0%
2017	312,335	11.9%
2018	298,628	11.4%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	50	0.0%
PPI use, post-index (day 1 to the end of follow-up)	1,271,662	48.3%

[1]All metrics based on total number of unique patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 1g. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	2,616,815	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	69.3	14.2
Age (years)	**Number**	**Percent**
<2	45	0.0%
2-11	319	0.0%
12-17	287	0.0%
18-39	120,408	4.6%
40-64	580,710	22.2%
65+	1,915,046	73.2%
Sex	**Number**	**Percent**
Female	1,733,690	66.3%
Male	883,125	33.7%
Other	0	0.0%
Year	**Number**	**Percent**
2010	157,687	6.0%
2011	301,601	11.5%
2012	270,852	10.4%
2013	279,880	10.7%
2014	276,460	10.6%
2015	274,818	10.5%
2016	358,320	13.7%
2017	351,250	13.4%
2018	345,947	13.2%
Recorded Dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	56	0.0%
PPI use, post-index (day 1 to the end of follow-up)	1,497,095	57.2%
Index Date Dispensing by Manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	527,698	20.2%
Ahp	1,290	0.0%
Amneal Pharmace	1,027,919	39.3%
Apotex Corp	11,272	0.4%
Bedford Labs	*****	0.0%
Boehringer Cons	*****	0.0%
Boehringer/Chat	17	0.0%
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	*****	0.0%
Covis/Teligent	0	0.0%
Dr.Reddy'S Lab	51,150	2.0%
Glaxo Pharm	0	0.0%
Glaxosmithkline	653	0.0%
Glenmark Pharma	560,286	21.4%
Gsms, Inc.	20	0.0%
Hi-Tech/Akorn C	2,466	0.1%
Major Pharmaceu	1,409	0.1%
Mylan	0	0.0%

Table 1g. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Index Date Dispensing by Manufacturer (Ranitidine only):	Number	Percent
Mylan Instituti	2,069	0.1%
Par Pharm.	23,206	0.9%
Pfizer Cons.Hlt	0	0.0%
Pharmaceutical	6,866	0.3%
Precision Dose	*****	0.0%
Ranbaxy Pharmac	*****	0.0%
Sandoz	170,508	6.5%
Silarx/Lannett	3,901	0.1%
Strides Pharma	0	0.0%
Teligent Pharma	0	0.0%
Teva Usa	394,536	15.1%
Watson Labs	*****	0.0%
Wockhardt Usa L	*****	0.0%
Zydus Pharmaceu	*****	0.0%

[1]All metrics based on total number of unique patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 1h. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	197,966	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	69.3	12.2
Age (years)	**Number**	**Percent**
<2	0	0.0%
2-11	*****	*****
12-17	*****	*****
18-39	6,721	3.4%
40-64	38,278	19.3%
65+	152,952	77.3%
Sex	**Number**	**Percent**
Female	121,857	61.6%
Male	76,109	38.4%
Other	0	0.0%
Year	**Number**	**Percent**
2010	14,540	7.3%
2011	36,012	18.2%
2012	22,512	11.4%
2013	24,074	12.2%
2014	30,983	15.7%
2015	27,447	13.9%
2016	23,690	12.0%
2017	7,509	3.8%
2018	11,199	5.7%
Recorded Dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	0	0.0%
PPI use, post-index (day 1 to the end of follow-up)	108,736	54.9%
Index Date Dispensing by Manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	735	0.4%
Ahp	*****	0.0%
Amneal Pharmace	930	0.5%
Apotex Corp	15	0.0%
Bedford Labs	146	0.1%
Boehringer Cons	0	0.0%
Boehringer/Chat	0	0.0%
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	142	0.1%
Covis/Teligent	*****	0.0%
Dr.Reddy'S Lab	19	0.0%
Glaxo Pharm	0	0.0%
Glaxosmithkline	0	0.0%
Glenmark Pharma	608	0.3%
Gsms, Inc.	0	0.0%
Hi-Tech/Akorn C	*****	0.0%
Major Pharmaceu	0	0.0%
Mylan	0	0.0%

Table 1h. Aggregated Baseline Table for Ranitidine, Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Index Date Dispensing by Manufacturer (Ranitidine only):	Number	Percent
Mylan Instituti	*****	0.0%
Par Pharm.	26	0.0%
Pfizer Cons.Hlt	0	0.0%
Pharmaceutical	*****	0.0%
Precision Dose	0	0.0%
Ranbaxy Pharmac	0	0.0%
Sandoz	148	0.1%
Silarx/Lannett	*****	0.0%
Strides Pharma	0	0.0%
Teligent Pharma	*****	0.0%
Teva Usa	625	0.3%
Watson Labs	0	0.0%
Wockhardt Usa L	0	0.0%
Zydus Pharmaceu	307	0.2%

[1]All metrics based on total number of unique patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 1i. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	2,793,675	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	69.3	14.0
Age (years)	**Number**	**Percent**
<2	45	0.0%
2-11	324	0.0%
12-17	295	0.0%
18-39	125,904	4.5%
40-64	613,231	22.0%
65+	2,053,876	73.5%
Sex	**Number**	**Percent**
Female	1,840,923	65.9%
Male	952,752	34.1%
Other	0	0.0%
Year	**Number**	**Percent**
2010	172,020	6.2%
2011	336,576	12.0%
2012	291,731	10.4%
2013	301,763	10.8%
2014	304,645	10.9%
2015	298,937	10.7%
2016	378,083	13.5%
2017	355,868	12.7%
2018	354,052	12.7%
Recorded Dispensing of:	**Number**	**Percent**
OTC ranitidine, on index date (day 0)	55	0.0%
PPI use, post-index (day 1 to the end of follow-up)	1,592,383	57.0%
Index Date Dispensing by Manufacturer (Ranitidine only):	**Number**	**Percent**
All Others	525,745	18.8%
Ahp	1,284	0.0%
Amneal Pharmace	1,023,082	36.6%
Apotex Corp	11,245	0.4%
Bedford Labs	145	0.0%
Boehringer Cons	*****	0.0%
Boehringer/Chat	17	0.0%
Chattem Cons Pr	0	0.0%
Covis Pharmaceu	133	0.0%
Covis/Teligent	*****	0.0%
Dr.Reddy'S Lab	50,955	1.8%
Glaxo Pharm	0	0.0%
Glaxosmithkline	648	0.0%
Glenmark Pharma	557,368	20.0%
Gsms, Inc.	20	0.0%
Hi-Tech/Akorn C	2,447	0.1%
Major Pharmaceu	1,408	0.1%
Mylan	0	0.0%

Table 1i. Aggregated Baseline Table for Ranitidine, Oral Solid/Liquid or Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Index Date Dispensing by Manufacturer (Ranitidine only):	Number	Percent
Mylan Instituti	2,066	0.1%
Par Pharm.	23,196	0.8%
Pfizer Cons.Hlt	0	0.0%
Pharmaceutical	6,835	0.2%
Precision Dose	*****	0.0%
Ranbaxy Pharmac	*****	0.0%
Sandoz	169,805	6.1%
Silarx/Lannett	3,875	0.1%
Strides Pharma	0	0.0%
Teligent Pharma	*****	0.0%
Teva Usa	393,185	14.1%
Watson Labs	*****	0.0%
Wockhardt Usa L	*****	0.0%
Zydus Pharmaceu	287	0.0%

[1]All metrics based on total number of unique patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 1j. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	1,881,674	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	70.6	14.5
Age (years)	**Number**	**Percent**
<2	*****	*****
2-11	*****	*****
12-17	217	0.0%
18-39	82,191	4.4%
40-64	388,580	20.7%
65+	1,410,588	75.0%
Sex	**Number**	**Percent**
Female	1,196,529	63.6%
Male	685,145	36.4%
Other	0	0.0%
Year	**Number**	**Percent**
2010	103,916	5.5%
2011	203,620	10.8%
2012	190,556	10.1%
2013	202,633	10.8%
2014	203,729	10.8%
2015	212,213	11.3%
2016	261,005	13.9%
2017	258,978	13.8%
2018	245,024	13.0%
Recorded Dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	24	0.0%
PPI use, post-index (day 1 to the end of follow-up)	906,062	48.2%

[1]All metrics based on total number of unique patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 1k. Aggregated Baseline Table for Famotidine, Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	16,247	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	67.5	14.4
Age (years)	**Number**	**Percent**
<2	0	0.0%
2-11	0	0.0%
12-17	*****	*****
18-39	*****	*****
40-64	3,824	23.5%
65+	11,386	70.1%
Sex	**Number**	**Percent**
Female	10,448	64.3%
Male	5,799	35.7%
Other	0	0.0%
Year	**Number**	**Percent**
2010	950	5.8%
2011	2,014	12.4%
2012	2,098	12.9%
2013	1,919	11.8%
2014	1,719	10.6%
2015	1,819	11.2%
2016	1,715	10.6%
2017	1,782	11.0%
2018	2,231	13.7%
Recorded Dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	0	0.0%
PPI use, post-index (day 1 to the end of follow-up)	9,332	57.4%

[1]All metrics based on total number of unique patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 1l. Aggregated Baseline Table for Famotidine, Oral Solid/Liquid or Injection/Intravenous (183-day washout, 30-day gap) in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018

Characteristic[1]	Number	Percent
Number of unique patients	1,895,931	
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	70.6	14.5
Age (years)	**Number**	**Percent**
<2	*****	0.0%
2-11	95	0.0%
12-17	218	0.0%
18-39	83,000	4.4%
40-64	391,832	20.7%
65+	1,420,783	74.9%
Sex	**Number**	**Percent**
Female	1,205,612	63.6%
Male	690,319	36.4%
Other	0	0.0%
Year	**Number**	**Percent**
2010	104,847	5.5%
2011	205,551	10.8%
2012	192,512	10.2%
2013	204,335	10.8%
2014	205,213	10.8%
2015	213,733	11.3%
2016	262,411	13.8%
2017	260,441	13.7%
2018	246,888	13.0%
Recorded dispensing of:	**Number**	**Percent**
OTC famotidine, on index date (day 0)	24	0.0%
PPI use, post-index (day 1 to the end of follow-up)	914,163	48.2%

[1]All metrics based on total number of unique patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 2a. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, All Episodes, in Days, Overall

			Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposure	Form	Design	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Ranitidine	Oral	0-day washout, 0-day gap	3,756,007	100.0%	874,190	23.3%	323,972	8.6%	347,239	9.2%	477,486	12.7%	514,481	13.7%	1,218,639	32.4%
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	264,585	100.0%	260,503	98.5%	2,930	1.1%	626	0.2%	406	0.2%	96	0.0%	24	0.0%
Ranitidine	Any	0-day washout, 0-day gap	3,968,029	100.0%	1,074,471	27.1%	331,616	8.4%	347,653	8.8%	480,699	12.1%	514,799	13.0%	1,218,791	30.7%
Famotidine	Oral	0-day washout, 0-day gap	2,612,985	100.0%	935,409	35.8%	237,653	9.1%	197,908	7.6%	292,391	11.2%	300,914	11.5%	648,710	24.8%
Famotidine	Inj/IV	0-day washout, 0-day gap	22,694	100.0%	20,295	89.4%	724	3.2%	474	2.1%	592	2.6%	297	1.3%	312	1.4%
Famotidine	Any	0-day washout, 0-day gap	2,630,636	100.0%	950,182	36.1%	238,738	9.1%	198,316	7.5%	293,134	11.1%	301,212	11.5%	649,054	24.7%
Ranitidine	Oral	183-day washout, 30-day gap	2,616,815	100.0%	709,989	27.1%	195,604	7.5%	276,381	10.6%	355,602	13.6%	365,820	14.0%	713,419	27.3%
Ranitidine	Inj/IV	183-day washout, 30-day gap	197,966	100.0%	138,324	69.9%	18,716	9.5%	15,053	7.6%	18,902	9.5%	5,178	2.6%	1,793	0.9%
Ranitidine	Any	183-day washout, 30-day gap	2,793,675	100.0%	821,290	29.4%	216,755	7.8%	290,678	10.4%	376,228	13.5%	371,971	13.3%	716,753	25.7%
Famotidine	Oral	183-day washout, 30-day gap	1,881,674	100.0%	758,342	40.3%	148,058	7.9%	153,320	8.1%	215,656	11.5%	211,051	11.2%	395,247	21.0%
Famotidine	Inj/IV	183-day washout, 30-day gap	16,247	100.0%	12,707	78.2%	1,184	7.3%	819	5.0%	988	6.1%	338	2.1%	211	1.3%
Famotidine	Any	183-day washout, 30-day gap	1,895,931	100.0%	768,336	40.5%	149,583	7.9%	154,165	8.1%	216,778	11.4%	211,474	11.2%	395,595	20.9%

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

[2] Injection/Intravenous

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 2b. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, All Episodes, in Days, by Sex

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid														
(0-day washout, 0-day gap)	3,756,007	100%	874,190	23.3%	323,972	8.6%	347,239	9.2%	477,486	12.7%	514,481	13.7%	1,218,639	32.4%
Female	*****	100%	*****	23.2%	*****	8.7%	*****	9.3%	*****	12.8%	*****	13.8%	*****	32.1%
Male	*****	100%	*****	23.4%	*****	8.5%	*****	9.1%	*****	12.5%	*****	13.5%	*****	33.0%
Other	*****	100%	*****	0.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
Ranitidine, Injection/ Intravenous														
(0-day washout, 0-day gap)	264,585	100%	260,503	98.5%	2,930	1.1%	626	0.2%	406	0.2%	96	0.0%	24	0.0%
Female	*****	100%	*****	98.4%	*****	1.1%	*****	0.2%	*****	0.2%	*****	0.0%	*****	0.0%
Male	*****	100%	*****	98.5%	*****	1.0%	*****	0.2%	*****	0.1%	*****	0.0%	*****	0.0%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Ranitidine, All														
(0-day washout, 0-day gap)	3,968,029	100%	1,074,471	27.1%	331,616	8.4%	347,653	8.8%	480,699	12.1%	514,799	13.0%	1,218,791	30.7%
Female	*****	100%	*****	26.7%	*****	8.5%	*****	8.9%	*****	12.3%	*****	13.1%	*****	30.5%
Male	*****	100%	*****	27.8%	*****	8.2%	*****	8.6%	*****	11.8%	*****	12.7%	*****	31.0%
Other	*****	100%	*****	0.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
Famotidine, Oral solid/liquid														
(0-day washout, 0-day gap)	2,612,985	100%	935,409	35.8%	237,653	9.1%	197,908	7.6%	292,391	11.2%	300,914	11.5%	648,710	24.8%
Female	*****	100%	*****	35.5%	*****	9.1%	*****	7.6%	*****	11.3%	*****	11.6%	*****	24.9%
Male	*****	100%	*****	36.3%	*****	9.1%	*****	7.5%	*****	11.1%	*****	11.3%	*****	24.8%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, Injection/Intravenous														
(0-day washout, 0-day gap)	22,694	100%	20,295	89.4%	724	3.2%	474	2.1%	592	2.6%	297	1.3%	312	1.4%
Female	*****	100%	*****	89.4%	*****	3.0%	*****	2.1%	*****	2.7%	*****	1.2%	*****	1.5%
Male	*****	100%	*****	89.4%	*****	3.5%	*****	2.1%	*****	2.5%	*****	1.5%	*****	1.1%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, All														
(0-day washout, 0-day gap)	2,630,636	100%	950,182	36.1%	238,738	9.1%	198,316	7.5%	293,134	11.1%	301,212	11.5%	649,054	24.7%
Female	*****	100%	*****	35.8%	*****	9.1%	*****	7.6%	*****	11.2%	*****	11.6%	*****	24.7%
Male	*****	100%	*****	36.6%	*****	9.0%	*****	7.4%	*****	11.0%	*****	11.3%	*****	24.6%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-

Table 2b. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, All Episodes, in Days, by Sex

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,616,815	100%	709,989	27.1%	195,604	7.5%	276,381	10.6%	355,602	13.6%	365,820	14.0%	713,419	27.3%
Female	*****	100%	*****	26.8%	*****	7.5%	*****	10.6%	*****	13.7%	*****	14.1%	*****	27.3%
Male	*****	100%	*****	27.7%	*****	7.4%	*****	10.6%	*****	13.4%	*****	13.8%	*****	27.2%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	197,966	100%	138,324	69.9%	18,716	9.5%	15,053	7.6%	18,902	9.5%	5,178	2.6%	1,793	0.9%
Female	*****	100%	*****	69.0%	*****	8.6%	*****	8.3%	*****	10.3%	*****	2.7%	*****	1.0%
Male	*****	100%	*****	71.3%	*****	10.8%	*****	6.4%	*****	8.3%	*****	2.4%	*****	0.8%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Ranitidine, All (183-day washout, 30-day gap)	2,793,675	100%	821,290	29.4%	216,755	7.8%	290,678	10.4%	376,228	13.5%	371,971	13.3%	716,753	25.7%
Female	*****	100%	*****	28.8%	*****	7.8%	*****	10.5%	*****	13.6%	*****	13.5%	*****	25.8%
Male	*****	100%	*****	30.5%	*****	7.8%	*****	10.3%	*****	13.1%	*****	13.0%	*****	25.3%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,881,674	100%	758,342	40.3%	148,058	7.9%	153,320	8.1%	215,656	11.5%	211,051	11.2%	395,247	21.0%
Female	*****	100%	*****	39.7%	*****	7.9%	*****	8.2%	*****	11.6%	*****	11.4%	*****	21.2%
Male	*****	100%	*****	41.3%	*****	7.8%	*****	8.0%	*****	11.3%	*****	11.0%	*****	20.6%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	16,247	100%	12,707	78.2%	1,184	7.3%	819	5.0%	988	6.1%	338	2.1%	211	1.3%
Female	*****	100%	*****	76.7%	*****	7.1%	*****	5.7%	*****	7.0%	*****	2.0%	*****	1.4%
Male	*****	100%	*****	80.9%	*****	7.6%	*****	3.8%	*****	4.4%	*****	2.2%	*****	1.1%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, All (183-day washout, 30-day gap)	1,895,931	100%	768,336	40.5%	149,583	7.9%	154,165	8.1%	216,778	11.4%	211,474	11.2%	395,595	20.9%
Female	*****	100%	*****	40.0%	*****	7.9%	*****	8.2%	*****	11.5%	*****	11.3%	*****	21.1%
Male	*****	100%	*****	41.5%	*****	7.9%	*****	8.0%	*****	11.3%	*****	10.9%	*****	20.5%
Other	-	100%	-	-	-	-	-	-	-	-	-	-	-	-

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 2c. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	3,756,007	100.0%	874,190	23.3%	323,972	8.6%	347,239	9.2%	477,486	12.7%	514,481	13.7%	1,218,639	32.4%
<2 years	*****	100.0%	*****	12.8%	*****	7.9%	*****	13.4%	*****	15.2%	*****	17.1%	*****	33.5%
2-11 years	*****	100.0%	*****	15.8%	*****	8.6%	*****	8.4%	*****	16.0%	*****	19.1%	*****	32.1%
12-17 years	*****	100.0%	*****	18.4%	*****	8.5%	*****	8.7%	*****	15.8%	*****	18.8%	*****	29.8%
18-39 years	*****	100.0%	*****	30.6%	*****	10.4%	*****	7.8%	*****	11.8%	*****	11.4%	*****	27.9%
40-64 years	*****	100.0%	*****	21.7%	*****	8.5%	*****	7.8%	*****	12.6%	*****	13.6%	*****	35.7%
65+ years	*****	100.0%	*****	23.3%	*****	8.5%	*****	9.8%	*****	12.8%	*****	13.9%	*****	31.6%
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	264,585	100.0%	260,503	98.5%	2,930	1.1%	626	0.2%	406	0.2%	96	0.0%	24	0.0%
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	98.9%	*****	0.7%	*****	0.1%	*****	0.2%	*****	0.1%	*****	0.0%
40-64 years	*****	100.0%	*****	98.5%	*****	1.1%	*****	0.2%	*****	0.2%	*****	0.1%	*****	0.0%
65+ years	*****	100.0%	*****	98.4%	*****	1.1%	*****	0.2%	*****	0.2%	*****	0.0%	*****	0.0%
Ranitidine, All (0-day washout, 0-day gap)	3,968,029	100.0%	1,074,471	27.1%	331,616	8.4%	347,653	8.8%	480,699	12.1%	514,799	13.0%	1,218,791	30.7%
<2 years	*****	100.0%	*****	12.8%	*****	7.9%	*****	13.4%	*****	15.2%	*****	17.1%	*****	33.5%
2-11 years	*****	100.0%	*****	16.6%	*****	8.5%	*****	8.3%	*****	15.9%	*****	18.9%	*****	31.8%
12-17 years	*****	100.0%	*****	19.3%	*****	8.9%	*****	8.5%	*****	15.3%	*****	18.7%	*****	29.2%
18-39 years	*****	100.0%	*****	32.5%	*****	10.3%	*****	7.6%	*****	11.6%	*****	11.0%	*****	26.9%
40-64 years	*****	100.0%	*****	24.7%	*****	8.4%	*****	7.5%	*****	12.1%	*****	13.1%	*****	34.2%
65+ years	*****	100.0%	*****	27.5%	*****	8.2%	*****	9.3%	*****	12.1%	*****	13.1%	*****	29.8%
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	2,612,985	100.0%	935,409	35.8%	237,653	9.1%	197,908	7.6%	292,391	11.2%	300,914	11.5%	648,710	24.8%
<2 years	*****	100.0%	*****	25.7%	*****	8.6%	*****	8.6%	*****	5.7%	*****	11.4%	*****	40.0%
2-11 years	*****	100.0%	*****	16.0%	*****	12.1%	*****	10.2%	*****	14.1%	*****	14.6%	*****	33.0%
12-17 years	*****	100.0%	*****	16.9%	*****	7.8%	*****	7.1%	*****	15.2%	*****	16.4%	*****	36.5%
18-39 years	*****	100.0%	*****	49.9%	*****	10.3%	*****	6.2%	*****	9.0%	*****	7.8%	*****	16.8%
40-64 years	*****	100.0%	*****	37.6%	*****	9.3%	*****	6.8%	*****	10.8%	*****	10.9%	*****	24.7%
65+ years	*****	100.0%	*****	34.4%	*****	9.0%	*****	7.9%	*****	11.4%	*****	11.9%	*****	25.3%

Sentinel

Table 2c. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	22,694	100.0%	20,295	89.4%	724	3.2%	474	2.1%	592	2.6%	297	1.3%	312	1.4%
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	0.0%	*****	0.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	85.4%	*****	3.0%	*****	2.1%	*****	3.1%	*****	2.3%	*****	4.2%
40-64 years	*****	100.0%	*****	87.1%	*****	3.5%	*****	2.3%	*****	2.8%	*****	1.6%	*****	2.7%
65+ years	*****	100.0%	*****	90.7%	*****	3.1%	*****	2.0%	*****	2.5%	*****	1.1%	*****	0.6%
Famotidine, All (0-day washout, 0-day gap)	2,630,636	100.0%	950,182	36.1%	238,738	9.1%	198,316	7.5%	293,134	11.1%	301,212	11.5%	649,054	24.7%
<2 years	*****	100.0%	*****	25.7%	*****	8.6%	*****	8.6%	*****	5.7%	*****	11.4%	*****	40.0%
2-11 years	*****	100.0%	*****	16.0%	*****	12.1%	*****	10.2%	*****	14.1%	*****	14.6%	*****	33.0%
12-17 years	*****	100.0%	*****	17.1%	*****	7.8%	*****	7.1%	*****	15.2%	*****	16.4%	*****	36.4%
18-39 years	*****	100.0%	*****	50.1%	*****	10.3%	*****	6.2%	*****	8.9%	*****	7.7%	*****	16.7%
40-64 years	*****	100.0%	*****	37.9%	*****	9.3%	*****	6.7%	*****	10.7%	*****	10.8%	*****	24.6%
65+ years	*****	100.0%	*****	34.8%	*****	8.9%	*****	7.9%	*****	11.4%	*****	11.9%	*****	25.2%
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,616,815	100.0%	709,989	27.1%	195,604	7.5%	276,381	10.6%	355,602	13.6%	365,820	14.0%	713,419	27.3%
<2 years	*****	100.0%	*****	6.7%	*****	0.0%	*****	13.3%	*****	20.0%	*****	22.2%	*****	37.8%
2-11 years	*****	100.0%	*****	18.5%	*****	8.2%	*****	5.0%	*****	18.8%	*****	20.4%	*****	29.2%
12-17 years	*****	100.0%	*****	18.5%	*****	6.3%	*****	7.7%	*****	19.5%	*****	19.9%	*****	28.2%
18-39 years	*****	100.0%	*****	35.4%	*****	9.0%	*****	8.6%	*****	12.8%	*****	11.6%	*****	22.5%
40-64 years	*****	100.0%	*****	26.4%	*****	7.5%	*****	8.9%	*****	13.6%	*****	14.2%	*****	29.5%
65+ years	*****	100.0%	*****	26.8%	*****	7.4%	*****	11.2%	*****	13.6%	*****	14.1%	*****	26.9%
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	197,966	100.0%	138,324	69.9%	18,716	9.5%	15,053	7.6%	18,902	9.5%	5,178	2.6%	1,793	0.9%
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	90.0%	*****	10.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	94.0%	*****	2.0%	*****	1.4%	*****	1.5%	*****	0.6%	*****	0.6%
40-64 years	*****	100.0%	*****	79.8%	*****	6.5%	*****	5.3%	*****	5.9%	*****	1.7%	*****	0.9%
65+ years	*****	100.0%	*****	66.3%	*****	10.5%	*****	8.5%	*****	10.8%	*****	2.9%	*****	0.9%

Table 2c. Distribution of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, All Episodes, in Days, by Age Group

	Total Patients		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, All (183-day washout, 30-day gap)	2,793,675	100.0%	821,290	29.4%	216,755	7.8%	290,678	10.4%	376,228	13.5%	371,971	13.3%	716,753	25.7%
<2 years	*****	100.0%	*****	6.7%	*****	0.0%	*****	13.3%	*****	20.0%	*****	22.2%	*****	37.8%
2-11 years	*****	100.0%	*****	19.8%	*****	8.0%	*****	4.9%	*****	18.5%	*****	20.1%	*****	28.7%
12-17 years	*****	100.0%	*****	20.0%	*****	6.8%	*****	7.5%	*****	19.0%	*****	19.3%	*****	27.5%
18-39 years	*****	100.0%	*****	37.3%	*****	9.0%	*****	8.4%	*****	12.4%	*****	11.2%	*****	21.7%
40-64 years	*****	100.0%	*****	28.7%	*****	7.6%	*****	8.7%	*****	13.3%	*****	13.6%	*****	28.0%
65+ years	*****	100.0%	*****	29.1%	*****	7.7%	*****	11.0%	*****	13.6%	*****	13.4%	*****	25.2%
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,881,674	100.0%	758,342	40.3%	148,058	7.9%	153,320	8.1%	215,656	11.5%	211,051	11.2%	395,247	21.0%
<2 years	*****	100.0%	*****	33.3%	*****	0.0%	*****	0.0%	*****	0.0%	*****	33.3%	*****	33.3%
2-11 years	*****	100.0%	*****	17.9%	*****	7.4%	*****	10.5%	*****	16.8%	*****	14.7%	*****	32.6%
12-17 years	*****	100.0%	*****	20.3%	*****	6.9%	*****	6.9%	*****	17.1%	*****	16.6%	*****	32.3%
18-39 years	*****	100.0%	*****	55.0%	*****	9.0%	*****	6.4%	*****	9.0%	*****	7.6%	*****	12.9%
40-64 years	*****	100.0%	*****	43.3%	*****	8.1%	*****	7.1%	*****	11.0%	*****	10.5%	*****	19.9%
65+ years	*****	100.0%	*****	38.6%	*****	7.7%	*****	8.5%	*****	11.7%	*****	11.6%	*****	21.8%
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	16,247	100.0%	12,707	78.2%	1,184	7.3%	819	5.0%	988	6.1%	338	2.1%	211	1.3%
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	86.6%	*****	2.8%	*****	2.1%	*****	3.1%	*****	2.1%	*****	3.3%
40-64 years	*****	100.0%	*****	82.1%	*****	5.7%	*****	3.1%	*****	4.7%	*****	2.1%	*****	2.1%
65+ years	*****	100.0%	*****	76.1%	*****	8.2%	*****	5.9%	*****	6.8%	*****	2.1%	*****	0.8%
Famotidine, All (183-day washout, 30-day gap)	1,895,931	100.0%	768,336	40.5%	149,583	7.9%	154,165	8.1%	216,778	11.4%	211,474	11.2%	395,595	20.9%
<2 years	*****	100.0%	*****	33.3%	*****	0.0%	*****	0.0%	*****	0.0%	*****	33.3%	*****	33.3%
2-11 years	*****	100.0%	*****	17.9%	*****	7.4%	*****	10.5%	*****	16.8%	*****	14.7%	*****	32.6%
12-17 years	*****	100.0%	*****	20.6%	*****	6.9%	*****	6.9%	*****	17.0%	*****	16.5%	*****	32.1%
18-39 years	*****	100.0%	*****	55.2%	*****	9.0%	*****	6.4%	*****	9.0%	*****	7.5%	*****	12.9%
40-64 years	*****	100.0%	*****	43.5%	*****	8.1%	*****	7.1%	*****	11.0%	*****	10.5%	*****	19.8%
65+ years	*****	100.0%	*****	38.8%	*****	7.8%	*****	8.5%	*****	11.7%	*****	11.6%	*****	21.6%

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 3a. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, All Episodes, in Days, Overall

Exposure	Form	Design	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	3,756,007	424.45	602.97	1	48	167	540	3,287
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	264,585	4.68	11.93	1	1	1	5	2,305
Ranitidine	Any	0-day washout, 0-day gap	3,968,029	402.07	594.18	1	30	148	508	3,287
Famotidine	Oral	0-day washout, 0-day gap	2,612,985	319.52	520.79	1	30	90	360	3,287
Famotidine	Inj/IV	0-day washout, 0-day gap	22,694	25.47	131.98	1	1	1	6	3,001
Famotidine	Any	0-day washout, 0-day gap	2,630,636	317.59	519.72	1	30	90	360	3,287
Ranitidine	Oral	183-day washout, 30-day gap	2,616,815	328.24	469.83	1	30	120	409	3,104
Ranitidine	Inj/IV	183-day washout, 30-day gap	197,966	36.19	79.85	1	1	1	44	2,207
Ranitidine	Any	183-day washout, 30-day gap	2,793,675	310.58	460.84	1	30	108	378	3,104
Famotidine	Oral	183-day washout, 30-day gap	1,881,674	255.90	424.37	1	30	71	285	3,104
Famotidine	Inj/IV	183-day washout, 30-day gap	16,247	33.35	114.18	1	1	1	24	2,732
Famotidine	Any	183-day washout, 30-day gap	1,895,931	254.34	423.35	1	30	70	282	3,104

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

[2] Injection/Intravenous

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 3b. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, All Episodes, in Days, by Sex

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	3,756,007	424.5	603.0	1	48	167	540	3,287
Female	*****	415.3	587.8	1	49	163	536	3,287
Male	*****	441.7	630.2	1	46	176	558	3,287
Other	*****	60.0	-	60	60	60	60	60
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	264,585	4.7	11.9	1	1	1	5	2,305
Female	*****	4.8	13.1	1	1	1	5	2,305
Male	*****	4.4	9.7	1	1	1	5	520
Other	-	-	-	-	-	-	-	-
Ranitidine, All (0-day washout, 0-day gap)	3,968,029	402.1	594.2	1	30	148	508	3,287
Female	*****	394.9	579.9	1	30	149	495	3,287
Male	*****	415.3	619.7	1	30	145	512	3,287
Other	*****	60.0	-	60	60	60	60	60
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	2,612,985	319.5	520.8	1	30	90	360	3,287
Female	*****	316.3	511.1	1	30	90	360	3,287
Male	*****	325.0	536.9	1	30	90	360	3,287
Other	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	22,694	25.5	132.0	1	1	1	6	3,001
Female	*****	26.6	137.2	1	1	1	6	2,812
Male	*****	23.5	121.8	1	1	1	5	3,001
Other	-	-	-	-	-	-	-	-
Famotidine, All (0-day washout, 0-day gap)	2,630,636	317.6	519.7	1	30	90	360	3,287
Female	*****	314.4	510.1	1	30	90	360	3,287
Male	*****	323.1	535.8	1	30	90	360	3,287
Other	-	-	-	-	-	-	-	-
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,616,815	328.2	469.8	1	30	120	409	3,104
Female	*****	326.8	464.6	1	30	120	410	3,104
Male	*****	331.0	479.9	1	30	120	408	3,103
Other	-	-	-	-	-	-	-	-
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	197,966	36.2	79.9	1	1	1	44	2,207
Female	*****	37.7	81.0	1	1	1	50	2,018
Male	*****	33.8	77.9	1	1	1	43	2,207
Other	-	-	-	-	-	-	-	-

Table 3b. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, All Episodes, in Days, by Sex

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, All (183-day washout, 30-day gap)	2,793,675	310.6	460.8	1	30	108	378	3,104
Female	*****	310.8	456.5	1	30	113	382	3,104
Male	*****	310.1	469.1	1	30	100	371	3,103
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,881,674	255.9	424.4	1	30	71	285	3,104
Female	*****	256.9	421.5	1	30	75	292	3,102
Male	*****	254.1	429.3	1	30	65	276	3,104
Other	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	16,247	33.4	114.2	1	1	1	24	2,732
Female	*****	35.6	118.9	1	1	1	28	2,732
Male	*****	29.4	105.0	1	1	1	22	2,700
Other	-	-	-	-	-	-	-	-
Famotidine, All (183-day washout, 30-day gap)	1,895,931	254.3	423.4	1	30	70	282	3,104
Female	*****	255.4	420.5	1	30	74	288	3,102
Male	*****	252.5	428.2	1	30	63	273	3,104
Other	-	-	-	-	-	-	-	-

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 3c. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, All Episodes, in Days, by Age Group

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	3,756,007	424.5	603.0	1	48	167	540	3,287
<2 years	*****	420.3	501.6	4	89	185	606	2,412
2-11 years	*****	336.0	360.6	2	66	199	491	2,424
12-17 years	*****	336.2	421.0	2	60	180	437	2,730
18-39 years	*****	393.9	633.9	1	30	114	450	3,287
40-64 years	*****	486.2	675.5	1	60	180	630	3,287
65+ years	*****	405.2	572.2	1	47	156	514	3,287
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	264,585	4.7	11.9	1	1	1	5	2,305
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	1.5	0.8	1	1	1	2	3
12-17 years	*****	1.5	1.0	1	1	1	2	4
18-39 years	*****	2.7	13.9	1	1	1	1	778
40-64 years	*****	4.2	17.3	1	1	1	3	2,305
65+ years	*****	4.9	9.8	1	1	2	6	467
Ranitidine, All (0-day washout, 0-day gap)	3,968,029	402.1	594.2	1	30	148	508	3,287
<2 years	*****	420.3	501.6	4	89	185	606	2,412
2-11 years	*****	332.9	360.4	1	60	195	480	2,424
12-17 years	*****	330.4	419.6	1	60	180	425	2,730
18-39 years	*****	380.7	626.9	1	30	90	420	3,287
40-64 years	*****	466.2	668.2	1	32	180	600	3,287
65+ years	*****	381.7	563.0	1	30	131	480	3,287
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	2,612,985	319.5	520.8	1	30	90	360	3,287
<2 years	*****	403.0	460.1	24	30	201	559	1,492
2-11 years	*****	323.3	361.7	6	60	170	458	2,190
12-17 years	*****	384.5	425.9	5	72	210	566	2,726
18-39 years	*****	241.0	501.3	1	20	31	180	3,287
40-64 years	*****	336.2	571.1	1	30	90	360	3,287
65+ years	*****	319.2	505.5	1	30	90	378	3,287
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	22,694	25.5	132.0	1	1	1	6	3,001
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	70.0	-	70	70	70	70	70
12-17 years	*****	1.0	-	1	1	1	1	1
18-39 years	*****	50.2	200.7	1	1	1	3	2,606
40-64 years	*****	41.6	202.6	1	1	1	5	3,001
65+ years	*****	17.4	81.4	1	1	1	6	2,683

Table 3c. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, All Episodes, in Days, by Age Group

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	2,630,636	317.6	519.7	1	30	90	360	3,287
<2 years	*****	403.0	460.1	24	30	201	559	1,492
2-11 years	*****	323.7	362.2	6	60	170	458	2,190
12-17 years	*****	383.6	425.8	1	68	210	561	2,726
18-39 years	*****	239.5	499.9	1	20	30	180	3,287
40-64 years	*****	334.2	569.9	1	30	90	360	3,287
65+ years	*****	317.2	504.4	1	30	90	373	3,287
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,616,815	328.2	469.8	1	30	120	409	3,104
<2 years	*****	453.7	504.0	18	106	266	593	2,234
2-11 years	*****	312.7	337.0	5	60	182	413	1,744
12-17 years	*****	309.2	354.9	3	62	178	421	2,338
18-39 years	*****	290.6	475.7	1	30	90	314	3,101
40-64 years	*****	362.8	514.2	1	30	138	455	3,104
65+ years	*****	320.1	454.6	1	30	120	400	3,104
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	197,966	36.2	79.9	1	1	1	44	2,207
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	1.6	0.9	1	1	1	2	3
12-17 years	*****	7.0	17.9	1	1	1	2	58
18-39 years	*****	11.5	64.8	1	1	1	1	1,307
40-64 years	*****	26.1	76.5	1	1	1	15	1,808
65+ years	*****	39.8	80.9	1	1	2	51	2,207
Ranitidine, All (183-day washout, 30-day gap)	2,793,675	310.6	460.8	1	30	108	378	3,104
<2 years	*****	453.7	504.0	18	106	266	593	2,234
2-11 years	*****	307.9	336.6	1	60	181	410	1,744
12-17 years	*****	301.1	353.5	1	60	170	415	2,338
18-39 years	*****	279.6	469.4	1	30	87	297	3,101
40-64 years	*****	346.1	506.6	1	30	120	428	3,104
65+ years	*****	301.9	445.2	1	30	106	369	3,104
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,881,674	255.9	424.4	1	30	71	285	3,104
<2 years	*****	381.3	361.4	30	30	362	752	752
2-11 years	*****	310.3	330.1	7	60	176	417	1,105
12-17 years	*****	355.2	404.6	5	60	181	535	2,317
18-39 years	*****	176.3	372.6	1	15	30	127	3,100
40-64 years	*****	252.7	443.4	1	30	60	265	3,102
65+ years	*****	261.4	421.4	1	30	87	301	3,104

Table 3c. Descriptive Statistics of Patients' Cumulative Exposure Duration in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, All Episodes, in Days, by Age Group

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	16,247	33.4	114.2	1	1	1	24	2,732
<2 years	-	-	-	-	-	-	-	-
2-11 years	-	-	-	-	-	-	-	-
12-17 years	*****	1.0	-	1	1	1	1	1
18-39 years	*****	43.1	175.2	1	1	1	2	1,879
40-64 years	*****	39.5	167.1	1	1	1	9	2,732
65+ years	*****	30.4	80.1	1	1	1	29	2,700
Famotidine, All (183-day washout, 30-day gap)	1,895,931	254.3	423.4	1	30	70	282	3,104
<2 years	*****	381.3	361.4	30	30	362	752	752
2-11 years	*****	310.3	330.1	7	60	176	417	1,105
12-17 years	*****	353.6	404.3	1	60	181	535	2,317
18-39 years	*****	175.3	371.6	1	15	30	126	3,100
40-64 years	*****	251.1	442.3	1	30	60	261	3,102
65+ years	*****	259.8	420.4	1	30	84	300	3,104

[1]Distribution of patients' cumulative exposure duration represents each patient's total episode length across all episodes

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 4a. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, Overall

			Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposure	**Form**	**Design**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine	Oral	0-day washout, 0-day gap	17,397,109	100.0%	9,307,892	53.5%	2,091,770	12.0%	3,031,452	17.4%	1,489,847	8.6%	843,758	4.8%	632,390	3.6%
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	1,127,985	100.0%	1,127,501	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Ranitidine	Any	0-day washout, 0-day gap	18,477,485	100.0%	10,386,452	56.2%	2,093,194	11.3%	3,031,582	16.4%	1,490,070	8.1%	843,789	4.6%	632,398	3.4%
Famotidine	Oral	0-day washout, 0-day gap	9,353,621	100.0%	5,169,572	55.3%	1,139,284	12.2%	1,423,975	15.2%	805,384	8.6%	464,973	5.0%	350,433	3.7%
Famotidine	Inj/IV	0-day washout, 0-day gap	64,393	100.0%	60,497	93.9%	1,932	3.0%	809	1.3%	789	1.2%	266	0.4%	100	0.2%
Famotidine	Any	0-day washout, 0-day gap	9,414,918	100.0%	5,227,028	55.5%	1,141,195	12.1%	1,424,735	15.1%	806,152	8.6%	465,252	4.9%	350,556	3.7%
Ranitidine	Oral	183-day washout, 30-day gap	4,953,948	100.0%	1,911,809	38.6%	301,159	6.1%	952,772	19.2%	638,088	12.9%	546,545	11.0%	603,575	12.2%
Ranitidine	Inj/IV	183-day washout, 30-day gap	261,533	100.0%	192,439	73.6%	26,363	10.1%	17,912	6.8%	20,471	7.8%	3,566	1.4%	782	0.3%
Ranitidine	Any	183-day washout, 30-day gap	5,220,293	100.0%	2,101,999	40.3%	329,662	6.3%	971,695	18.6%	660,309	12.6%	551,225	10.6%	605,403	11.6%
Famotidine	Oral	183-day washout, 30-day gap	2,982,163	100.0%	1,363,360	45.7%	192,736	6.5%	426,891	14.3%	348,965	11.7%	300,936	10.1%	349,275	11.7%
Famotidine	Inj/IV	183-day washout, 30-day gap	19,550	100.0%	15,612	79.9%	1,421	7.3%	943	4.8%	1,074	5.5%	328	1.7%	172	0.9%
Famotidine	Any	183-day washout, 30-day gap	3,001,957	100.0%	1,378,527	45.9%	194,397	6.5%	427,942	14.3%	350,198	11.7%	301,353	10.0%	349,540	11.6%

[1]Distribution of all episode durations represents each episode's total episode length across all patients

[2]Injection/Intravenous

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 4b. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Sex

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid														
(0-day washout, 0-day gap)	17,397,109	100.0%	9,307,892	53.5%	2,091,770	12.0%	3,031,452	17.4%	1,489,847	8.6%	843,758	4.8%	632,390	3.6%
Female	*****	100.0%	*****	54.2%	*****	12.0%	*****	17.2%	*****	8.4%	*****	4.7%	*****	3.5%
Male	*****	100.0%	*****	52.2%	*****	12.0%	*****	17.9%	*****	8.8%	*****	5.1%	*****	4.0%
Other	*****	100.0%	*****	0.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
Ranitidine, Injection/intravenous														
(0-day washout, 0-day gap)	1,127,985	100.0%	1,127,501	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Female	*****	100.0%	*****	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Male	*****	100.0%	*****	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ranitidine, All														
(0-day washout, 0-day gap)	18,477,485	100.0%	10,386,452	56.2%	2,093,194	11.3%	3,031,582	16.4%	1,490,070	8.1%	843,789	4.6%	632,398	3.4%
Female	*****	100.0%	*****	56.8%	*****	11.4%	*****	16.2%	*****	7.9%	*****	4.5%	*****	3.3%
Male	*****	100.0%	*****	55.2%	*****	11.3%	*****	16.8%	*****	8.3%	*****	4.8%	*****	3.7%
Other	*****	100.0%	*****	0.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
Famotidine, Oral solid/liquid														
(0-day washout, 0-day gap)	9,353,621	100.0%	5,169,572	55.3%	1,139,284	12.2%	1,423,975	15.2%	805,384	8.6%	464,973	5.0%	350,433	3.7%
Female	*****	100.0%	*****	55.8%	*****	12.2%	*****	15.0%	*****	8.5%	*****	4.9%	*****	3.6%
Male	*****	100.0%	*****	54.3%	*****	12.2%	*****	15.6%	*****	8.9%	*****	5.1%	*****	3.9%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous														
(0-day washout, 0-day gap)	64,393	100.0%	60,497	93.9%	1,932	3.0%	809	1.3%	789	1.2%	266	0.4%	100	0.2%
Female	*****	100.0%	*****	94.0%	*****	2.9%	*****	1.2%	*****	1.2%	*****	0.4%	*****	0.2%
Male	*****	100.0%	*****	93.8%	*****	3.1%	*****	1.3%	*****	1.2%	*****	0.4%	*****	0.1%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, All														
(0-day washout, 0-day gap)	9,414,918	100.0%	5,227,028	55.5%	1,141,195	12.1%	1,424,735	15.1%	806,152	8.6%	465,252	4.9%	350,556	3.7%
Female	*****	100.0%	*****	56.1%	*****	12.1%	*****	14.9%	*****	8.4%	*****	4.8%	*****	3.6%
Male	*****	100.0%	*****	54.5%	*****	12.2%	*****	15.5%	*****	8.8%	*****	5.1%	*****	3.9%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 4b. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Sex

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid														
(183-day washout, 30-day gap)	4,953,948	100.0%	1,911,809	38.6%	301,159	6.1%	952,772	19.2%	638,088	12.9%	546,545	11.0%	603,575	12.2%
Female	*****	100.0%	*****	38.9%	*****	6.1%	*****	19.3%	*****	12.9%	*****	11.0%	*****	11.9%
Male	*****	100.0%	*****	38.0%	*****	6.1%	*****	19.1%	*****	12.9%	*****	11.1%	*****	12.7%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ranitidine, Injection/intravenous														
(183-day washout, 30-day gap)	261,533	100.0%	192,439	73.6%	26,363	10.1%	17,912	6.8%	20,471	7.8%	3,566	1.4%	782	0.3%
Female	*****	100.0%	*****	72.7%	*****	9.6%	*****	7.5%	*****	8.6%	*****	1.4%	*****	0.3%
Male	*****	100.0%	*****	75.0%	*****	10.8%	*****	5.8%	*****	6.7%	*****	1.4%	*****	0.3%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ranitidine, All														
(183-day washout, 30-day gap)	5,220,293	100.0%	2,101,999	40.3%	329,662	6.3%	971,695	18.6%	660,309	12.6%	551,225	10.6%	605,403	11.6%
Female	*****	100.0%	*****	40.4%	*****	6.3%	*****	18.7%	*****	12.7%	*****	10.5%	*****	11.4%
Male	*****	100.0%	*****	40.0%	*****	6.4%	*****	18.4%	*****	12.5%	*****	10.6%	*****	12.0%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid														
(183-day washout, 30-day gap)	2,982,163	100.0%	1,363,360	45.7%	192,736	6.5%	426,891	14.3%	348,965	11.7%	300,936	10.1%	349,275	11.7%
Female	*****	100.0%	*****	45.7%	*****	6.4%	*****	14.5%	*****	11.7%	*****	10.1%	*****	11.5%
Male	*****	100.0%	*****	45.7%	*****	6.5%	*****	13.9%	*****	11.7%	*****	10.1%	*****	12.0%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous														
(183-day washout, 30-day gap)	19,550	100.0%	15,612	79.9%	1,421	7.3%	943	4.8%	1,074	5.5%	328	1.7%	172	0.9%
Female	*****	100.0%	*****	78.6%	*****	7.3%	*****	5.4%	*****	6.1%	*****	1.6%	*****	1.0%
Male	*****	100.0%	*****	82.1%	*****	7.2%	*****	3.8%	*****	4.3%	*****	1.9%	*****	0.7%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Famotidine, All														
(183-day washout, 30-day gap)	3,001,957	100.0%	1,378,527	45.9%	194,397	6.5%	427,942	14.3%	350,198	11.7%	301,353	10.0%	349,540	11.6%
Female	*****	100.0%	*****	45.9%	*****	6.4%	*****	14.5%	*****	11.7%	*****	10.0%	*****	11.5%
Male	*****	100.0%	*****	45.9%	*****	6.6%	*****	13.8%	*****	11.7%	*****	10.1%	*****	12.0%
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-

[1]Distribution of all episode durations represents each episode's total episode length across all patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 4c. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Age Group

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid														
(0-day washout, 0-day gap)	17,397,109	100.0%	9,307,892	53.5%	2,091,770	12.0%	3,031,452	17.4%	1,489,847	8.6%	843,758	4.8%	632,390	3.6%
<2 years	*****	100.0%	*****	54.3%	*****	21.4%	*****	8.5%	*****	8.0%	*****	4.1%	*****	3.8%
2-11 years	*****	100.0%	*****	59.9%	*****	17.4%	*****	7.4%	*****	7.3%	*****	4.6%	*****	3.5%
12-17 years	*****	100.0%	*****	63.8%	*****	14.9%	*****	8.6%	*****	7.4%	*****	3.2%	*****	2.1%
18-39 years	*****	100.0%	*****	63.5%	*****	12.3%	*****	10.7%	*****	6.7%	*****	3.7%	*****	3.2%
40-64 years	*****	100.0%	*****	57.9%	*****	12.7%	*****	13.8%	*****	7.9%	*****	4.3%	*****	3.4%
65+ years	*****	100.0%	*****	50.8%	*****	11.7%	*****	19.6%	*****	9.0%	*****	5.2%	*****	3.8%
Ranitidine, Injection/intravenous														
(0-day washout, 0-day gap)	1,127,985	100.0%	1,127,501	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
12-17 years	*****	100.0%	*****	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
18-39 years	*****	100.0%	*****	99.8%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
40-64 years	*****	100.0%	*****	99.9%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
65+ years	*****	100.0%	*****	100.0%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Ranitidine, All														
(0-day washout, 0-day gap)	18,477,485	100.0%	10,386,452	56.2%	2,093,194	11.3%	3,031,582	16.4%	1,490,070	8.1%	843,789	4.6%	632,398	3.4%
<2 years	*****	100.0%	*****	54.4%	*****	21.3%	*****	8.5%	*****	8.0%	*****	4.0%	*****	3.8%
2-11 years	*****	100.0%	*****	60.1%	*****	17.3%	*****	7.4%	*****	7.3%	*****	4.6%	*****	3.4%
12-17 years	*****	100.0%	*****	64.1%	*****	14.8%	*****	8.5%	*****	7.4%	*****	3.2%	*****	2.1%
18-39 years	*****	100.0%	*****	64.2%	*****	12.0%	*****	10.4%	*****	6.6%	*****	3.6%	*****	3.2%
40-64 years	*****	100.0%	*****	59.4%	*****	12.3%	*****	13.3%	*****	7.6%	*****	4.2%	*****	3.3%
65+ years	*****	100.0%	*****	54.3%	*****	10.9%	*****	18.2%	*****	8.4%	*****	4.8%	*****	3.5%
Famotidine, Oral solid/liquid														
(0-day washout, 0-day gap)	9,353,621	100.0%	5,169,572	55.3%	1,139,284	12.2%	1,423,975	15.2%	805,384	8.6%	464,973	5.0%	350,433	3.7%
<2 years	*****	100.0%	*****	67.0%	*****	10.4%	*****	9.5%	*****	6.8%	*****	5.0%	*****	1.4%
2-11 years	*****	100.0%	*****	65.6%	*****	13.6%	*****	7.1%	*****	7.3%	*****	4.0%	*****	2.3%
12-17 years	*****	100.0%	*****	60.0%	*****	16.4%	*****	9.5%	*****	7.7%	*****	4.1%	*****	2.4%
18-39 years	*****	100.0%	*****	66.5%	*****	11.3%	*****	9.4%	*****	6.3%	*****	3.4%	*****	3.0%
40-64 years	*****	100.0%	*****	59.5%	*****	12.4%	*****	12.5%	*****	7.8%	*****	4.4%	*****	3.5%
65+ years	*****	100.0%	*****	53.2%	*****	12.2%	*****	16.5%	*****	9.0%	*****	5.3%	*****	3.9%

Table 4c. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Age Group

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Famotidine, Injection/intravenous														
(0-day washout, 0-day gap)	64,393	100.0%	60,497	93.9%	1,932	3.0%	809	1.3%	789	1.2%	266	0.4%	100	0.2%
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	86.9%	*****	6.4%	*****	2.7%	*****	2.3%	*****	1.2%	*****	0.5%
40-64 years	*****	100.0%	*****	90.0%	*****	4.6%	*****	2.0%	*****	2.2%	*****	0.8%	*****	0.3%
65+ years	*****	100.0%	*****	96.0%	*****	2.1%	*****	0.8%	*****	0.8%	*****	0.2%	*****	0.1%
Famotidine, All														
(0-day washout, 0-day gap)	9,414,918	100.0%	5,227,028	55.5%	1,141,195	12.1%	1,424,735	15.1%	806,152	8.6%	465,252	4.9%	350,556	3.7%
<2 years	*****	100.0%	*****	67.0%	*****	10.4%	*****	9.5%	*****	6.8%	*****	5.0%	*****	1.4%
2-11 years	*****	100.0%	*****	65.8%	*****	13.5%	*****	7.1%	*****	7.3%	*****	4.0%	*****	2.3%
12-17 years	*****	100.0%	*****	60.1%	*****	16.3%	*****	9.5%	*****	7.7%	*****	4.1%	*****	2.4%
18-39 years	*****	100.0%	*****	66.7%	*****	11.2%	*****	9.4%	*****	6.3%	*****	3.4%	*****	3.0%
40-64 years	*****	100.0%	*****	59.7%	*****	12.3%	*****	12.4%	*****	7.8%	*****	4.4%	*****	3.4%
65+ years	*****	100.0%	*****	53.5%	*****	12.1%	*****	16.4%	*****	8.9%	*****	5.2%	*****	3.9%
Ranitidine, Oral solid/liquid														
(183-day washout, 30-day gap)	4,953,948	100.0%	1,911,809	38.6%	301,159	6.1%	952,772	19.2%	638,088	12.9%	546,545	11.0%	603,575	12.2%
<2 years	*****	100.0%	*****	25.3%	*****	8.8%	*****	15.4%	*****	15.4%	*****	20.9%	*****	14.3%
2-11 years	*****	100.0%	*****	31.5%	*****	10.1%	*****	8.8%	*****	19.7%	*****	15.1%	*****	14.9%
12-17 years	*****	100.0%	*****	34.2%	*****	7.0%	*****	12.0%	*****	17.1%	*****	17.7%	*****	12.0%
18-39 years	*****	100.0%	*****	50.6%	*****	5.8%	*****	14.2%	*****	11.6%	*****	8.5%	*****	9.3%
40-64 years	*****	100.0%	*****	41.4%	*****	5.9%	*****	16.7%	*****	13.4%	*****	10.8%	*****	11.8%
65+ years	*****	100.0%	*****	36.8%	*****	6.2%	*****	20.5%	*****	12.8%	*****	11.3%	*****	12.5%
Ranitidine, Injection/intravenous														
(183-day washout, 30-day gap)	261,533	100.0%	192,439	73.6%	26,363	10.1%	17,912	6.8%	20,471	7.8%	3,566	1.4%	782	0.3%
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	92.3%	*****	7.7%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	93.3%	*****	2.7%	*****	1.5%	*****	1.6%	*****	0.7%	*****	0.2%
40-64 years	*****	100.0%	*****	81.5%	*****	7.2%	*****	5.0%	*****	5.0%	*****	1.1%	*****	0.3%
65+ years	*****	100.0%	*****	70.8%	*****	11.1%	*****	7.5%	*****	8.8%	*****	1.5%	*****	0.3%

Table 4c. Distribution of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Age Group

	Total Episodes		1-30		31-60		61-90		91-183		184-365		366+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, All														
(183-day washout, 30-day gap)	5,220,293	100.0%	2,101,999	40.3%	329,662	6.3%	971,695	18.6%	660,309	12.6%	551,225	10.6%	605,403	11.6%
<2 years	*****	100.0%	*****	25.3%	*****	8.8%	*****	15.4%	*****	15.4%	*****	20.9%	*****	14.3%
2-11 years	*****	100.0%	*****	32.5%	*****	10.0%	*****	8.6%	*****	19.4%	*****	14.8%	*****	14.7%
12-17 years	*****	100.0%	*****	35.9%	*****	7.0%	*****	11.6%	*****	16.6%	*****	17.2%	*****	11.6%
18-39 years	*****	100.0%	*****	51.9%	*****	5.7%	*****	13.8%	*****	11.3%	*****	8.3%	*****	9.0%
40-64 years	*****	100.0%	*****	42.9%	*****	6.0%	*****	16.2%	*****	13.1%	*****	10.4%	*****	11.3%
65+ years	*****	100.0%	*****	38.6%	*****	6.5%	*****	19.8%	*****	12.6%	*****	10.8%	*****	11.9%
Famotidine, Oral solid/liquid														
(183-day washout, 30-day gap)	2,982,163	100.0%	1,363,360	45.7%	192,736	6.5%	426,891	14.3%	348,965	11.7%	300,936	10.1%	349,275	11.7%
<2 years	*****	100.0%	*****	28.6%	*****	14.3%	*****	14.3%	*****	0.0%	*****	42.9%	*****	0.0%
2-11 years	*****	100.0%	*****	29.5%	*****	10.7%	*****	12.8%	*****	16.1%	*****	12.8%	*****	18.1%
12-17 years	*****	100.0%	*****	36.3%	*****	5.5%	*****	13.9%	*****	16.4%	*****	12.8%	*****	15.1%
18-39 years	*****	100.0%	*****	62.6%	*****	5.5%	*****	9.8%	*****	8.7%	*****	6.4%	*****	7.1%
40-64 years	*****	100.0%	*****	50.4%	*****	6.1%	*****	12.5%	*****	11.5%	*****	9.2%	*****	10.3%
65+ years	*****	100.0%	*****	43.3%	*****	6.6%	*****	15.1%	*****	11.9%	*****	10.6%	*****	12.4%
Famotidine, Injection/intravenous														
(183-day washout, 30-day gap)	19,550	100.0%	15,612	79.9%	1,421	7.3%	943	4.8%	1,074	5.5%	328	1.7%	172	0.9%
<2 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2-11 years	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	85.9%	*****	3.6%	*****	1.8%	*****	4.0%	*****	2.3%	*****	2.4%
40-64 years	*****	100.0%	*****	82.6%	*****	5.6%	*****	3.4%	*****	4.4%	*****	2.0%	*****	1.8%
65+ years	*****	100.0%	*****	78.3%	*****	8.2%	*****	5.6%	*****	6.0%	*****	1.5%	*****	0.4%
Famotidine, All														
(183-day washout, 30-day gap)	3,001,957	100.0%	1,378,527	45.9%	194,397	6.5%	427,942	14.3%	350,198	11.7%	301,353	10.0%	349,540	11.6%
<2 years	*****	100.0%	*****	28.6%	*****	14.3%	*****	14.3%	*****	0.0%	*****	42.9%	*****	0.0%
2-11 years	*****	100.0%	*****	29.5%	*****	10.7%	*****	12.8%	*****	16.1%	*****	12.8%	*****	18.1%
12-17 years	*****	100.0%	*****	36.4%	*****	5.5%	*****	13.9%	*****	16.4%	*****	12.8%	*****	15.0%
18-39 years	*****	100.0%	*****	62.7%	*****	5.5%	*****	9.7%	*****	8.6%	*****	6.4%	*****	7.1%
40-64 years	*****	100.0%	*****	50.6%	*****	6.1%	*****	12.4%	*****	11.5%	*****	9.2%	*****	10.2%
65+ years	*****	100.0%	*****	43.5%	*****	6.6%	*****	15.1%	*****	11.9%	*****	10.5%	*****	12.3%

[1]Distribution of all episode durations represents each episode's total episode length across all patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 5a. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, Overall

Exposure	Form	Design	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	17,397,109	91.6	171.2	1	30	30	90	3,287
Ranitidine	Inj/IV[2]	0-day washout, 0-day gap	1,127,985	1.1	2.5	1	1	1	1	1,139
Ranitidine	Any	0-day washout, 0-day gap	18,477,485	86.3	167.5	1	30	30	90	3,287
Famotidine	Oral	0-day washout, 0-day gap	9,353,621	89.3	167.7	1	30	30	90	3,287
Famotidine	Inj/IV	0-day washout, 0-day gap	64,393	9.0	34.5	1	1	1	3	1,485
Famotidine	Any	0-day washout, 0-day gap	9,414,918	88.7	167.3	1	30	30	90	3,287
Ranitidine	Oral	183-day washout, 30-day gap	4,953,948	173.4	294.3	1	30	83	180	3,104
Ranitidine	Inj/IV	183-day washout, 30-day gap	261,533	27.4	54.8	1	1	1	36	2,001
Ranitidine	Any	183-day washout, 30-day gap	5,220,293	166.2	289.0	1	30	73	167	3,104
Famotidine	Oral	183-day washout, 30-day gap	2,982,163	161.5	290.4	1	30	60	156	3,104
Famotidine	Inj/IV	183-day washout, 30-day gap	19,550	27.7	85.1	1	1	1	22	2,531
Famotidine	Any	183-day washout, 30-day gap	3,001,957	160.6	289.8	1	30	60	155	3,104

[1]Distribution of all episode durations represents each episode's total episode length across all patients

[2]Injection/Intravenous

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 5b. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Sex

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	17,397,109	91.6	171.2	1	30	30	90	3,287
Female	*****	89.2	163.7	1	30	30	90	3,287
Male	*****	96.2	184.5	1	30	30	90	3,287
Other	*****	60.0	-	60	60	60	60	60
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	1,127,985	1.1	2.5	1	1	1	1	1,139
Female	*****	1.1	2.8	1	1	1	1	1,139
Male	*****	1.1	1.6	1	1	1	1	292
Other	-	-	-	-	-	-	-	-
Ranitidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	18,477,485	86.3	167.5	1	30	30	90	3,287
Female	*****	84.2	160.3	1	30	30	90	3,287
Male	*****	90.4	180.2	1	30	30	90	3,287
Other	*****	60.0	-	60	60	60	60	60
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	9,353,621	89.3	167.7	1	30	30	90	3,287
Female	*****	87.5	162.6	1	30	30	90	3,287
Male	*****	92.3	176.2	1	30	30	90	3,287
Other	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	64,393	9.0	34.5	1	1	1	3	1,485
Female	*****	8.9	34.8	1	1	1	3	1,485
Male	*****	9.1	33.7	1	1	1	2	1,322
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	9,414,918	88.7	167.3	1	30	30	90	3,287
Female	*****	87.0	162.2	1	30	30	90	3,287
Male	*****	91.8	175.8	1	30	30	90	3,287
Other	-	-	-	-	-	-	-	-
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	4,953,948	173.4	294.3	1	30	83	180	3,104
Female	*****	170.0	286.8	1	30	82	180	3,104
Male	*****	180.5	309.1	1	30	86	180	3,103
Other	-	-	-	-	-	-	-	-
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	261,533	27.4	54.8	1	1	1	36	2,001
Female	*****	28.4	55.7	1	1	1	42	2,001
Male	*****	25.7	53.2	1	1	1	30	1,996
Other	-	-	-	-	-	-	-	-

Table 5b. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Sex

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	5,220,293	166.2	289.0	1	30	73	167	3,104
Female	*****	163.6	282.0	1	30	73	164	3,104
Male	*****	171.6	302.5	1	30	74	175	3,103
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	2,982,163	161.5	290.4	1	30	60	156	3,104
Female	*****	159.3	284.5	1	30	60	155	3,102
Male	*****	165.5	301.0	1	30	60	161	3,104
Other	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	19,550	27.7	85.1	1	1	1	22	2,531
Female	*****	29.4	87.2	1	1	1	25	1,654
Male	*****	24.7	80.9	1	1	1	21	2,531
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	3,001,957	160.6	289.8	1	30	60	155	3,104
Female	*****	158.4	283.8	1	30	60	153	3,102
Male	*****	164.6	300.3	1	30	60	159	3,104
Other	-	-	-	-	-	-	-	-

[1]Distribution of all episode durations represents each episode's total episode length across all patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 5c. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	17,397,109	91.6	171.2	1	30	30	90	3,287
<2 years	*****	82.3	146.3	1	30	30	60	1,506
2-11 years	*****	77.0	124.8	1	30	30	60	1,422
12-17 years	*****	68.0	113.3	1	30	30	60	1,944
18-39 years	*****	82.4	188.6	1	30	30	60	3,287
40-64 years	*****	87.9	182.4	1	30	30	90	3,287
65+ years	*****	94.0	164.5	1	30	30	90	3,287
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	1,127,985	1.1	2.5	1	1	1	1	1,139
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	1.1	0.3	1	1	1	1	2
12-17 years	*****	1.1	0.3	1	1	1	1	2
18-39 years	*****	1.3	5.4	1	1	1	1	364
40-64 years	*****	1.2	4.4	1	1	1	1	1,139
65+ years	*****	1.1	1.6	1	1	1	1	224
Ranitidine, All (0-day washout, 0-day gap)	18,477,485	86.3	167.5	1	30	30	90	3,287
<2 years	*****	82.1	146.2	1	30	30	60	1,506
2-11 years	*****	76.6	124.6	1	30	30	60	1,422
12-17 years	*****	67.4	112.9	1	30	30	60	1,944
18-39 years	*****	80.7	187.0	1	30	30	60	3,287
40-64 years	*****	84.8	179.8	1	30	30	90	3,287
65+ years	*****	87.4	160.4	1	30	30	90	3,287
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	9,353,621	89.3	167.7	1	30	30	90	3,287
<2 years	*****	63.8	96.4	4	30	30	60	1,017
2-11 years	*****	65.1	100.0	2	29	30	60	1,085
12-17 years	*****	72.5	109.3	1	30	30	60	1,230
18-39 years	*****	75.9	179.0	1	30	30	60	3,287
40-64 years	*****	85.4	179.1	1	30	30	90	3,287
65+ years	*****	91.3	163.0	1	30	30	90	3,287
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	64,393	9.0	34.5	1	1	1	3	1,485
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	14.0	9.0	6	7	10	21	26
12-17 years	*****	1.0	-	1	1	1	1	1
18-39 years	*****	18.2	56.4	1	1	4	13	1,485
40-64 years	*****	14.6	46.0	1	1	1	9	1,322
65+ years	*****	6.1	25.4	1	1	1	1	1,059

Table 5c. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	9,414,918	88.7	167.3	1	30	30	90	3,287
<2 years	*****	63.8	96.4	4	30	30	60	1,017
2-11 years	*****	64.9	99.8	2	29	30	60	1,085
12-17 years	*****	72.4	109.3	1	30	30	60	1,230
18-39 years	*****	75.3	178.2	1	30	30	60	3,287
40-64 years	*****	84.9	178.6	1	30	30	90	3,287
65+ years	*****	90.8	162.6	1	30	30	90	3,287
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	4,953,948	173.4	294.3	1	30	83	180	3,104
<2 years	*****	224.4	319.2	14	30	91	288	2,019
2-11 years	*****	190.4	250.4	1	30	90	214	1,519
12-17 years	*****	168.7	213.6	3	30	90	213	1,581
18-39 years	*****	145.3	289.7	1	30	30	120	3,101
40-64 years	*****	172.2	307.1	1	30	68	170	3,104
65+ years	*****	175.7	289.9	1	30	90	180	3,104
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	261,533	27.4	54.8	1	1	1	36	2,001
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	1.0	0.0	1	1	1	1	1
12-17 years	*****	5.4	15.5	1	1	1	1	57
18-39 years	*****	9.2	36.2	1	1	1	1	826
40-64 years	*****	20.1	50.5	1	1	1	16	1,724
65+ years	*****	29.9	56.2	1	1	1	43	2,001
Ranitidine, All (183-day washout, 30-day gap)	5,220,293	166.2	289.0	1	30	73	167	3,104
<2 years	*****	224.4	319.2	14	30	91	288	2,019
2-11 years	*****	187.5	249.6	1	30	90	212	1,519
12-17 years	*****	164.2	212.3	1	30	90	210	1,581
18-39 years	*****	140.9	286.0	1	30	30	119	3,101
40-64 years	*****	166.4	302.7	1	30	63	159	3,104
65+ years	*****	167.9	284.2	1	30	83	177	3,104
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	2,982,163	161.5	290.4	1	30	60	156	3,104
<2 years	*****	163.4	145.7	30	30	79	332	354
2-11 years	*****	197.8	263.8	4	30	86	212	1,105
12-17 years	*****	176.0	227.2	5	30	84	211	1,269
18-39 years	*****	112.6	254.8	1	17	30	90	3,100
40-64 years	*****	150.0	292.7	1	30	30	132	3,102
65+ years	*****	167.7	291.3	1	30	61	175	3,104

Table 5c. Descriptive Statistics of All Episode Durations in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	19,550	27.7	85.1	1	1	1	22	2,531
<2 years	-	-	-	-	-	-	-	-
2-11 years	-	-	-	-	-	-	-	-
12-17 years	*****	1.0	-	1	1	1	1	1
18-39 years	*****	35.5	138.9	1	1	1	3	1,654
40-64 years	*****	32.4	117.0	1	1	1	15	1,871
65+ years	*****	25.4	62.5	1	1	1	28	2,531
Famotidine, All (183-day washout, 30-day gap)	3,001,957	160.6	289.8	1	30	60	155	3,104
<2 years	*****	163.4	145.7	30	30	79	332	354
2-11 years	*****	197.8	263.8	4	30	86	212	1,105
12-17 years	*****	175.6	227.1	1	30	84	211	1,269
18-39 years	*****	111.9	254.0	1	15	30	90	3,100
40-64 years	*****	149.2	292.0	1	30	30	131	3,102
65+ years	*****	166.9	290.7	1	30	60	173	3,104

[1]Distribution of all episode durations represents each episode's total episode length across all patients

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 6a. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, Overall

			Total Dispensings		1-30		31-60		61-90		91+	
Exposure	**Form**	**Design**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine	Oral	0-day washout, 0-day gap	40,798,365	100.0%	32,412,996	79.4%	1,599,518	3.9%	6,784,037	16.6%	1,814	0.0%
Ranitidine	Inj/IV[1]	0-day washout, 0-day gap	1,180,911	100.0%	1,180,854	100.0%	*****	*****	*****	*****	*****	*****
Ranitidine	Any	0-day washout, 0-day gap	41,979,218	100.0%	33,593,795	80.0%	1,599,553	3.8%	6,784,055	16.2%	1,815	0.0%
Famotidine	Oral	0-day washout, 0-day gap	23,258,433	100.0%	19,090,232	82.1%	1,083,036	4.7%	3,084,267	13.3%	898	0.0%
Famotidine	Inj/IV	0-day washout, 0-day gap	109,228	100.0%	109,089	99.9%	*****	*****	*****	*****	*****	*****
Famotidine	Any	0-day washout, 0-day gap	23,367,198	100.0%	19,198,872	82.2%	1,083,143	4.6%	3,084,281	13.2%	902	0.0%
Ranitidine	Oral	183-day washout, 30-day gap	20,879,922	100.0%	16,549,510	79.3%	770,832	3.7%	3,558,947	17.0%	633	0.0%
Ranitidine	Inj/IV	183-day washout, 30-day gap	833,443	100.0%	833,407	100.0%	*****	*****	*****	*****	*****	*****
Ranitidine	Any	183-day washout, 30-day gap	21,786,059	100.0%	17,450,435	80.1%	771,905	3.5%	3,563,085	16.4%	634	0.0%
Famotidine	Oral	183-day washout, 30-day gap	12,959,871	100.0%	10,682,579	82.4%	572,879	4.4%	1,704,089	13.1%	324	0.0%
Famotidine	Inj/IV	183-day washout, 30-day gap	65,773	100.0%	65,697	99.9%	*****	*****	*****	*****	*****	*****
Famotidine	Any	183-day washout, 30-day gap	13,032,818	100.0%	10,755,096	82.5%	573,051	4.4%	1,704,343	13.1%	328	0.0%

[1]Injection/Intravenous

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 6b. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Sex

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	40,798,365	100.0%	32,412,996	79.4%	1,599,518	3.9%	6,784,037	16.6%	1,814	0.0%
Female	*****	100.0%	*****	80.0%	*****	3.7%	*****	16.3%	*****	0.0%
Male	*****	100.0%	*****	78.4%	*****	4.3%	*****	17.3%	*****	0.0%
Other	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	1,180,911	100.0%	1,180,854	100.0%	*****	*****	*****	*****	*****	*****
Female	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
Male	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-
Ranitidine, All (0-day washout, 0-day gap)	41,979,218	100.0%	33,593,795	80.0%	1,599,553	3.8%	6,784,055	16.2%	1,815	0.0%
Female	*****	100.0%	*****	80.6%	*****	3.6%	*****	15.8%	*****	0.0%
Male	*****	100.0%	*****	79.1%	*****	4.2%	*****	16.8%	*****	0.0%
Other	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	23,258,433	100.0%	19,090,232	82.1%	1,083,036	4.7%	3,084,267	13.3%	898	0.0%
Female	*****	100.0%	*****	82.7%	*****	4.6%	*****	12.8%	*****	0.0%
Male	*****	100.0%	*****	81.1%	*****	4.8%	*****	14.1%	*****	0.0%
	-	-	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	109,228	100.0%	109,089	99.9%	*****	*****	*****	*****	*****	*****
Female	*****	100.0%	*****	99.9%	*****	0.1%	*****	0.0%	*****	0.0%
Male	*****	100.0%	*****	99.8%	*****	0.1%	*****	0.0%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-
Famotidine, All (0-day washout, 0-day gap)	23,367,198	100.0%	19,198,872	82.2%	1,083,143	4.6%	3,084,281	13.2%	902	0.0%
Female	*****	100.0%	*****	82.8%	*****	4.6%	*****	12.7%	*****	0.0%
Male	*****	100.0%	*****	81.1%	*****	4.8%	*****	14.1%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	20,879,922	100.0%	16,549,510	79.3%	770,832	3.7%	3,558,947	17.0%	633	0.0%
Female	*****	100.0%	*****	79.7%	*****	3.6%	*****	16.7%	*****	0.0%
Male	*****	100.0%	*****	78.4%	*****	3.9%	*****	17.7%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-

Table 6b. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Sex

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	833,443	100.0%	833,407	100.0%	*****	*****	*****	*****	*****	*****
Female	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
Male	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-
Ranitidine, All (183-day washout, 30-day gap)	21,786,059	100.0%	17,450,435	80.1%	771,905	3.5%	3,563,085	16.4%	634	0.0%
Female	*****	100.0%	*****	80.5%	*****	3.4%	*****	16.1%	*****	0.0%
Male	*****	100.0%	*****	79.3%	*****	3.8%	*****	16.9%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	12,959,871	100.0%	10,682,579	82.4%	572,879	4.4%	1,704,089	13.1%	324	0.0%
Female	*****	100.0%	*****	82.9%	*****	4.4%	*****	12.8%	*****	0.0%
Male	*****	100.0%	*****	81.6%	*****	4.5%	*****	13.8%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	65,773	100.0%	65,697	99.9%	*****	*****	*****	*****	*****	*****
Female	*****	100.0%	*****	99.9%	*****	0.1%	*****	0.0%	*****	0.0%
Male	*****	100.0%	*****	99.9%	*****	0.1%	*****	0.0%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-
Famotidine, All (183-day washout, 30-day gap)	13,032,818	100.0%	10,755,096	82.5%	573,051	4.4%	1,704,343	13.1%	328	0.0%
Female	*****	100.0%	*****	83.0%	*****	4.3%	*****	12.7%	*****	0.0%
Male	*****	100.0%	*****	81.7%	*****	4.5%	*****	13.8%	*****	0.0%
Other	-	-	-	-	-	-	-	-	-	-

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 6c. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Age Group

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	40,798,365	100.0%	32,412,996	79.4%	1,599,518	3.9%	6,784,037	16.6%	1,814	0.0%
<2 years	*****	100.0%	*****	92.4%	*****	5.4%	*****	2.2%	*****	0.0%
2-11 years	*****	100.0%	*****	93.2%	*****	4.9%	*****	1.9%	*****	0.0%
12-17 years	*****	100.0%	*****	94.9%	*****	2.0%	*****	3.1%	*****	0.0%
18-39 years	*****	100.0%	*****	87.0%	*****	6.0%	*****	7.0%	*****	0.0%
40-64 years	*****	100.0%	*****	85.0%	*****	4.1%	*****	10.9%	*****	0.0%
65+ years	*****	100.0%	*****	76.2%	*****	3.7%	*****	20.1%	*****	0.0%
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	1,180,911	100.0%	1,180,854	100.0%	*****	*****	*****	*****	*****	*****
<2 years	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
40-64 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
65+ years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
Ranitidine, All (0-day washout, 0-day gap)	41,979,218	100.0%	33,593,795	80.0%	1,599,553	3.8%	6,784,055	16.2%	1,815	0.0%
<2 years	*****	100.0%	*****	92.4%	*****	5.4%	*****	2.2%	*****	0.0%
2-11 years	*****	100.0%	*****	93.2%	*****	4.9%	*****	1.9%	*****	0.0%
12-17 years	*****	100.0%	*****	94.9%	*****	2.0%	*****	3.1%	*****	0.0%
18-39 years	*****	100.0%	*****	87.1%	*****	5.9%	*****	7.0%	*****	0.0%
40-64 years	*****	100.0%	*****	85.2%	*****	4.0%	*****	10.7%	*****	0.0%
65+ years	*****	100.0%	*****	77.0%	*****	3.5%	*****	19.4%	*****	0.0%
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	23,258,433	100.0%	19,090,232	82.1%	1,083,036	4.7%	3,084,267	13.3%	898	0.0%
<2 years	*****	100.0%	*****	98.0%	*****	1.8%	*****	0.2%	*****	0.0%
2-11 years	*****	100.0%	*****	91.7%	*****	6.3%	*****	2.0%	*****	0.0%
12-17 years	*****	100.0%	*****	93.5%	*****	2.6%	*****	3.9%	*****	0.0%
18-39 years	*****	100.0%	*****	88.4%	*****	5.7%	*****	5.9%	*****	0.0%
40-64 years	*****	100.0%	*****	86.0%	*****	4.9%	*****	9.1%	*****	0.0%
65+ years	*****	100.0%	*****	80.4%	*****	4.5%	*****	15.1%	*****	0.0%

Table 6c. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Age Group

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	109,228	100.0%	109,089	99.9%	*****	*****	*****	*****	*****	*****
<2 years	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	99.8%	*****	0.1%	*****	0.1%	*****	0.0%
40-64 years	*****	100.0%	*****	99.9%	*****	0.1%	*****	0.0%	*****	0.0%
65+ years	*****	100.0%	*****	99.9%	*****	0.1%	*****	0.0%	*****	0.0%
Famotidine, All (0-day washout, 0-day gap)	23,367,198	100.0%	19,198,872	82.2%	1,083,143	4.6%	3,084,281	13.2%	902	0.0%
<2 years	*****	100.0%	*****	98.0%	*****	1.8%	*****	0.2%	*****	0.0%
2-11 years	*****	100.0%	*****	91.7%	*****	6.3%	*****	2.0%	*****	0.0%
12-17 years	*****	100.0%	*****	93.5%	*****	2.6%	*****	3.9%	*****	0.0%
18-39 years	*****	100.0%	*****	88.5%	*****	5.6%	*****	5.9%	*****	0.0%
40-64 years	*****	100.0%	*****	86.1%	*****	4.8%	*****	9.0%	*****	0.0%
65+ years	*****	100.0%	*****	80.4%	*****	4.5%	*****	15.0%	*****	0.0%
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	20,879,922	100.0%	16,549,510	79.3%	770,832	3.7%	3,558,947	17.0%	633	0.0%
<2 years	*****	100.0%	*****	90.8%	*****	7.1%	*****	2.1%	*****	0.0%
2-11 years	*****	100.0%	*****	93.4%	*****	5.0%	*****	1.5%	*****	0.0%
12-17 years	*****	100.0%	*****	94.7%	*****	2.3%	*****	3.0%	*****	0.0%
18-39 years	*****	100.0%	*****	87.2%	*****	4.9%	*****	7.8%	*****	0.0%
40-64 years	*****	100.0%	*****	85.0%	*****	3.7%	*****	11.3%	*****	0.0%
65+ years	*****	100.0%	*****	76.5%	*****	3.6%	*****	19.9%	*****	0.0%
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	833,443	100.0%	833,407	100.0%	*****	*****	*****	*****	*****	*****
<2 years	-	-	-	-	-	-	-	-	-	-
2-11 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
40-64 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
65+ years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%

Table 6c. Distribution of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, by Length Categories, in Days, by Age Group

	Total Dispensings		1-30		31-60		61-90		91+	
Exposures	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Ranitidine, All (183-day washout, 30-day gap)	21,786,059	100.0%	17,450,435	80.1%	771,905	3.5%	3,563,085	16.4%	634	0.0%
<2 years	*****	100.0%	*****	90.8%	*****	7.1%	*****	2.1%	*****	0.0%
2-11 years	*****	100.0%	*****	93.5%	*****	5.0%	*****	1.5%	*****	0.0%
12-17 years	*****	100.0%	*****	94.7%	*****	2.3%	*****	3.0%	*****	0.0%
18-39 years	*****	100.0%	*****	87.4%	*****	4.8%	*****	7.7%	*****	0.0%
40-64 years	*****	100.0%	*****	85.4%	*****	3.6%	*****	11.0%	*****	0.0%
65+ years	*****	100.0%	*****	77.6%	*****	3.4%	*****	18.9%	*****	0.0%
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	12,959,871	100.0%	10,682,579	82.4%	572,879	4.4%	1,704,089	13.1%	324	0.0%
<2 years	*****	100.0%	*****	97.1%	*****	0.0%	*****	2.9%	*****	0.0%
2-11 years	*****	100.0%	*****	94.9%	*****	4.1%	*****	1.1%	*****	0.0%
12-17 years	*****	100.0%	*****	95.1%	*****	2.0%	*****	3.0%	*****	0.0%
18-39 years	*****	100.0%	*****	89.1%	*****	4.7%	*****	6.2%	*****	0.0%
40-64 years	*****	100.0%	*****	86.7%	*****	4.5%	*****	8.8%	*****	0.0%
65+ years	*****	100.0%	*****	80.9%	*****	4.4%	*****	14.7%	*****	0.0%
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	65,773	100.0%	65,697	99.9%	*****	*****	*****	*****	*****	*****
<2 years	-	-	-	-	-	-	-	-	-	-
2-11 years	-	-	-	-	-	-	-	-	-	-
12-17 years	*****	100.0%	*****	100.0%	*****	0.0%	*****	0.0%	*****	0.0%
18-39 years	*****	100.0%	*****	99.7%	*****	0.1%	*****	0.2%	*****	0.0%
40-64 years	*****	100.0%	*****	99.9%	*****	0.0%	*****	0.0%	*****	0.0%
65+ years	*****	100.0%	*****	99.9%	*****	0.1%	*****	0.0%	*****	0.0%
Famotidine, All (183-day washout, 30-day gap)	13,032,818	100.0%	10,755,096	82.5%	573,051	4.4%	1,704,343	13.1%	328	0.0%
<2 years	*****	100.0%	*****	97.1%	*****	0.0%	*****	2.9%	*****	0.0%
2-11 years	*****	100.0%	*****	94.9%	*****	4.1%	*****	1.1%	*****	0.0%
12-17 years	*****	100.0%	*****	95.1%	*****	2.0%	*****	3.0%	*****	0.0%
18-39 years	*****	100.0%	*****	89.3%	*****	4.6%	*****	6.1%	*****	0.0%
40-64 years	*****	100.0%	*****	86.8%	*****	4.4%	*****	8.7%	*****	0.0%
65+ years	*****	100.0%	*****	80.9%	*****	4.4%	*****	14.7%	*****	0.0%

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 7a. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, Overall

Exposure	Form	Design	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	40,798,365	39.1	23.3	1	30	30	30	473
Ranitidine	Inj/IV[1]	0-day washout, 0-day gap	1,180,911	1.1	1.1	1	1	1	1	364
Ranitidine	Any	0-day washout, 0-day gap	41,979,218	38.0	23.8	1	30	30	30	473
Famotidine	Oral	0-day washout, 0-day gap	23,258,433	35.9	22.2	1	30	30	30	365
Famotidine	Inj/IV	0-day washout, 0-day gap	109,228	5.3	6.4	1	1	4	7	180
Famotidine	Any	0-day washout, 0-day gap	23,367,198	35.8	22.3	1	30	30	30	365
Ranitidine	Oral	183-day washout, 30-day gap	20,879,922	39.1	23.7	1	30	30	30	300
Ranitidine	Inj/IV	183-day washout, 30-day gap	833,443	1.0	1.0	1	1	1	1	364
Ranitidine	Any	183-day washout, 30-day gap	21,786,059	37.5	24.4	1	30	30	30	364
Famotidine	Oral	183-day washout, 30-day gap	12,959,871	35.4	22.5	1	30	30	30	360
Famotidine	Inj/IV	183-day washout, 30-day gap	65,773	4.7	6.2	1	1	1	7	180
Famotidine	Any	183-day washout, 30-day gap	13,032,818	35.2	22.5	1	30	30	30	360

[1]Injection/Intravenous

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 7b. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Sex

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	40,798,365	39.1	23.3	1	30	30	30	473
Female	*****	38.8	23.1	1	30	30	30	300
Male	*****	39.5	23.5	1	30	30	30	473
Other	*****	30.0	0.0	30	30	30	30	30
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	1,180,911	1.1	1.1	1	1	1	1	364
Female	*****	1.1	1.1	1	1	1	1	364
Male	*****	1.0	0.9	1	1	1	1	84
Other	-	-	-	-	-	-	-	-
Ranitidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	41,979,218	38.0	23.8	1	30	30	30	473
Female	*****	37.8	23.6	1	30	30	30	364
Male	*****	38.4	24.1	1	30	30	30	473
Other	*****	30.0	0.0	30	30	30	30	30
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	23,258,433	35.9	22.2	1	30	30	30	365
Female	*****	35.5	21.9	1	30	30	30	180
Male	*****	36.5	22.7	1	30	30	30	365
Other	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	109,228	5.3	6.4	1	1	4	7	180
Female	*****	5.2	6.1	1	1	4	7	180
Male	*****	5.6	7.1	1	1	3	7	90
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid or Injection/intravenous (0-day washout, 0-day gap)	23,367,198	35.8	22.3	1	30	30	30	365
Female	*****	35.4	22.0	1	30	30	30	180
Male	*****	36.4	22.7	1	30	30	30	365
Other	-	-	-	-	-	-	-	-
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	20,879,922	39.1	23.7	1	30	30	30	300
Female	*****	38.8	23.5	1	30	30	30	300
Male	*****	39.5	24.0	1	30	30	30	300
Other	-	-	-	-	-	-	-	-
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	833,443	1.0	1.0	1	1	1	1	364
Female	*****	1.1	1.1	1	1	1	1	364
Male	*****	1.0	0.9	1	1	1	1	84
Other	-	-	-	-	-	-	-	-

Table 7b. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Sex

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	21,786,059	37.5	24.4	1	30	30	30	364
Female	*****	37.4	24.2	1	30	30	30	364
Male	*****	37.9	24.7	1	30	30	30	300
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	12,959,871	35.4	22.5	1	30	30	30	360
Female	*****	35.1	22.2	1	30	30	30	180
Male	*****	35.9	22.8	1	30	30	30	360
Other	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	65,773	4.7	6.2	1	1	1	7	180
Female	*****	4.6	6.0	1	1	1	7	180
Male	*****	5.0	6.6	1	1	1	7	90
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid or Injection/intravenous (183-day washout, 30-day gap)	13,032,818	35.2	22.5	1	30	30	30	360
Female	*****	34.9	22.3	1	30	30	30	180
Male	*****	35.8	22.9	1	30	30	30	360
Other	-	-	-	-	-	-	-	-

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 7c. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	40,798,365	39.1	23.3	1	30	30	30	473
<2 years	*****	30.9	9.5	1	30	30	30	90
2-11 years	*****	30.6	9.5	1	30	30	30	100
12-17 years	*****	31.4	11.3	1	30	30	30	90
18-39 years	*****	33.2	16.4	1	30	30	30	300
40-64 years	*****	35.8	19.5	1	30	30	30	473
65+ years	*****	41.1	25.0	1	30	30	30	473
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	1,180,911	1.1	1.1	1	1	1	1	364
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	1.0	0.0	1	1	1	1	1
12-17 years	*****	1.0	0.0	1	1	1	1	1
18-39 years	*****	1.2	2.9	1	1	1	1	364
40-64 years	*****	1.1	1.3	1	1	1	1	90
65+ years	*****	1.0	0.9	1	1	1	1	90
Ranitidine, All (0-day washout, 0-day gap)	41,979,218	38.0	23.8	1	30	30	30	473
<2 years	*****	30.9	9.5	1	30	30	30	90
2-11 years	*****	30.6	9.6	1	30	30	30	100
12-17 years	*****	31.2	11.6	1	30	30	30	90
18-39 years	*****	32.9	16.6	1	30	30	30	364
40-64 years	*****	35.2	19.8	1	30	30	30	473
65+ years	*****	39.7	25.7	1	30	30	30	473
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	23,258,433	35.9	22.2	1	30	30	30	365
<2 years	*****	28.8	5.0	4	28	30	30	90
2-11 years	*****	29.4	10.6	2	27	30	30	90
12-17 years	*****	31.8	12.8	1	30	30	30	90
18-39 years	*****	31.5	16.1	1	30	30	30	100
40-64 years	*****	33.6	19.0	1	30	30	30	180
65+ years	*****	36.9	23.4	1	30	30	30	365
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	109,228	5.3	6.4	1	1	4	7	180
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	6.4	2.1	2	6	7	7	9
12-17 years	*****	1.0	-	1	1	1	1	1
18-39 years	*****	6.6	5.4	1	5	7	7	88
40-64 years	*****	6.2	5.8	1	1	7	7	180
65+ years	*****	4.5	6.9	1	1	1	7	90

Table 7c. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	23,367,198	35.8	22.3	1	30	30	30	365
<2 years	*****	28.8	5.0	4	28	30	30	90
2-11 years	*****	29.3	10.7	2	27	30	30	90
12-17 years	*****	31.8	12.8	1	30	30	30	90
18-39 years	*****	31.1	16.3	1	30	30	30	100
40-64 years	*****	33.4	19.0	1	30	30	30	180
65+ years	*****	36.8	23.5	1	30	30	30	365
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	20,879,922	39.1	23.7	1	30	30	30	300
<2 years	*****	30.7	9.7	3	30	30	30	90
2-11 years	*****	30.2	8.7	1	30	30	30	90
12-17 years	*****	31.3	11.3	1	30	30	30	90
18-39 years	*****	33.5	17.3	1	30	30	30	300
40-64 years	*****	35.8	20.0	1	30	30	30	300
65+ years	*****	40.7	25.2	1	30	30	30	300
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	833,443	1.0	1.0	1	1	1	1	364
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	1.0	0.0	1	1	1	1	1
12-17 years	*****	1.0	0.0	1	1	1	1	1
18-39 years	*****	1.2	3.3	1	1	1	1	364
40-64 years	*****	1.1	1.3	1	1	1	1	90
65+ years	*****	1.0	0.9	1	1	1	1	84
Ranitidine, All (183-day washout, 30-day gap)	21,786,059	37.5	24.4	1	30	30	30	364
<2 years	*****	30.7	9.7	3	30	30	30	90
2-11 years	*****	30.1	8.8	1	30	30	30	90
12-17 years	*****	31.0	11.6	1	30	30	30	90
18-39 years	*****	33.0	17.6	1	30	30	30	364
40-64 years	*****	35.0	20.4	1	30	30	30	300
65+ years	*****	38.8	26.0	1	30	30	30	300
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	12,959,871	35.4	22.5	1	30	30	30	360
<2 years	*****	28.6	11.0	25	25	25	30	90
2-11 years	*****	28.8	8.2	2	25	30	30	90
12-17 years	*****	30.7	11.9	1	30	30	30	90
18-39 years	*****	31.0	16.9	1	30	30	30	93
40-64 years	*****	32.9	19.1	1	30	30	30	180
65+ years	*****	36.3	23.5	1	30	30	30	360

Table 7c. Descriptive Statistics of Days Supplied Per Dispensing in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	65,773	4.7	6.2	1	1	1	7	180
<2 years	-	-	-	-	-	-	-	-
2-11 years	-	-	-	-	-	-	-	-
12-17 years	*****	1.0	-	1	1	1	1	1
18-39 years	*****	5.9	4.8	1	4	7	7	88
40-64 years	*****	5.8	5.8	1	1	7	7	180
65+ years	*****	4.0	6.5	1	1	1	6	90
Famotidine, All (183-day washout, 30-day gap)	13,032,818	35.2	22.5	1	30	30	30	360
<2 years	*****	28.6	11.0	25	25	25	30	90
2-11 years	*****	28.8	8.2	2	25	30	30	90
12-17 years	*****	30.7	12.0	1	30	30	30	90
18-39 years	*****	30.6	17.0	1	30	30	30	93
40-64 years	*****	32.7	19.2	1	30	30	30	180
65+ years	*****	36.2	23.5	1	30	30	30	360

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 8a. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, Overall

Exposure	Form	Design	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine	Oral	0-day washout, 0-day gap	13,641,102	58.5	187.1	1	3	11	36	3,248
Ranitidine	Inj/IV[1]	0-day washout, 0-day gap	863,400	30.9	112.8	1	6	13	20	3,143
Ranitidine	Any	0-day washout, 0-day gap	14,509,456	58.1	187.9	1	4	11	34	3,248
Famotidine	Oral	0-day washout, 0-day gap	6,740,636	56.3	187.8	1	3	10	32	3,244
Famotidine	Inj/IV	0-day washout, 0-day gap	41,699	31.7	119.3	1	6	7	20	2,824
Famotidine	Any	0-day washout, 0-day gap	6,784,282	56.4	188.3	1	3	10	32	3,244
Ranitidine	Oral	183-day washout, 30-day gap	2,337,133	191.2	309.0	31	46	81	181	3,075
Ranitidine	Inj/IV	183-day washout, 30-day gap	63,567	189.9	298.9	31	41	66	187	2,983
Ranitidine	Any	183-day washout, 30-day gap	2,426,618	195.7	316.6	31	46	82	185	3,075
Famotidine	Oral	183-day washout, 30-day gap	1,100,489	199.9	326.7	31	46	81	185	3,052
Famotidine	Inj/IV	183-day washout, 30-day gap	3,303	190.0	292.3	31	43	75	180	2,365
Famotidine	Any	183-day washout, 30-day gap	1,106,026	200.7	327.9	31	46	81	186	3,052

[1]Injection/Intravenous

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 8b. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Sex

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	13,641,102	58.5	187.1	1	3	11	36	3,248
Female	*****	61.0	193.2	1	3	11	37	3,240
Male	*****	53.7	174.6	1	3	10	33	3,248
Other	-	-	-	-	-	-	-	-
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	863,400	30.9	112.8	1	6	13	20	3,143
Female	*****	31.0	114.2	1	6	13	20	3,111
Male	*****	30.6	110.3	1	6	13	20	3,143
Other	-	-	-	-	-	-	-	-
Ranitidine, All (0-day washout, 0-day gap)	14,509,456	58.1	187.9	1	4	11	34	3,248
Female	*****	60.6	194.2	1	4	12	35	3,242
Male	*****	53.4	175.3	1	3	10	33	3,248
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	6,740,636	56.3	187.8	1	3	10	32	3,244
Female	*****	58.8	193.5	1	3	10	33	3,244
Male	*****	51.9	177.3	1	3	9	30	3,222
	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	41,699	31.7	119.3	1	6	7	20	2,824
Female	*****	31.5	121.2	1	6	7	20	2,824
Male	*****	32.3	114.7	1	6	8	20	2,587
Other	-	-	-	-	-	-	-	-
Famotidine, All (0-day washout, 0-day gap)	6,784,282	56.4	188.3	1	3	10	32	3,244
Female	*****	58.8	194.0	1	3	10	33	3,244
Male	*****	52.0	177.7	1	3	9	30	3,222
Other	-	-	-	-	-	-	-	-
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,337,133	191.2	309.0	31	46	81	181	3,075
Female	*****	195.1	314.7	31	46	82	185	3,075
Male	*****	182.7	296.1	31	46	80	173	3,044
Other	-	-	-	-	-	-	-	-
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	63,567	189.9	298.9	31	41	66	187	2,983
Female	*****	195.3	302.5	31	41	69	195	2,983
Male	*****	180.8	292.5	31	41	62	174	2,846
Other	-	-	-	-	-	-	-	-

Table 8b. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Sex

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, All (183-day washout, 30-day gap)	2,426,618	195.7	316.6	31	46	82	185	3,075
Female	*****	199.8	322.5	31	47	83	189	3,075
Male	*****	186.8	303.3	31	46	80	176	3,044
Other	-	-	-	-	-	-	-	-
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,100,489	199.9	326.7	31	46	81	185	3,052
Female	*****	203.4	331.3	31	46	82	189	3,052
Male	*****	192.8	317.3	31	45	79	178	3,029
Other	-	-	-	-	-	-	-	-
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	3,303	190.0	292.3	31	43	75	180	2,365
Female	*****	196.0	304.7	31	42	76	193	2,365
Male	*****	177.7	265.2	31	44	74	168	2,093
Other	-	-	-	-	-	-	-	-
Famotidine, All (183-day washout, 30-day gap)	1,106,026	200.7	327.9	31	46	81	186	3,052
Female	*****	204.2	332.6	31	46	82	190	3,052
Male	*****	193.5	318.3	31	45	79	178	3,029
Other	-	-	-	-	-	-	-	-

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Table 8c. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Ranitidine, Oral solid/liquid (0-day washout, 0-day gap)	13,641,102	58.5	187.1	1	3	11	36	3,248
<2 years	*****	64.0	191.5	1	4	12	31	1,970
2-11 years	*****	44.4	156.1	1	3	9	27	2,329
12-17 years	*****	46.9	155.8	1	4	11	30	2,739
18-39 years	*****	74.2	230.6	1	4	13	40	3,200
40-64 years	*****	57.9	189.1	1	3	11	35	3,248
65+ years	*****	57.6	182.3	1	3	11	36	3,240
Ranitidine, Injection/intravenous (0-day washout, 0-day gap)	863,400	30.9	112.8	1	6	13	20	3,143
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	78.7	40.6	40	40	75	121	121
12-17 years	*****	92.3	124.2	2	27	31	137	327
18-39 years	*****	82.3	229.1	1	6	20	34	2,983
40-64 years	*****	38.1	136.1	1	6	13	22	3,143
65+ years	*****	28.6	104.4	1	6	13	20	3,079
Ranitidine, All (0-day washout, 0-day gap)	14,509,456	58.1	187.9	1	4	11	34	3,248
<2 years	*****	65.4	194.2	1	4	12	32	1,970
2-11 years	*****	44.3	153.6	1	3	9	27	2,329
12-17 years	*****	48.8	160.6	1	4	11	31	2,739
18-39 years	*****	76.1	235.3	1	4	13	41	3,200
40-64 years	*****	58.5	191.9	1	3	11	34	3,248
65+ years	*****	56.7	182.2	1	4	11	34	3,245
Famotidine, Oral solid/liquid (0-day washout, 0-day gap)	6,740,636	56.3	187.8	1	3	10	32	3,244
<2 years	*****	43.0	143.6	1	3	10	31	1,391
2-11 years	*****	39.4	145.4	1	4	10	24	2,089
12-17 years	*****	53.3	191.3	1	4	9	31	2,530
18-39 years	*****	86.2	261.3	1	4	12	41	3,239
40-64 years	*****	61.3	203.1	1	3	10	33	3,219
65+ years	*****	53.0	177.2	1	3	9	31	3,244
Famotidine, Injection/intravenous (0-day washout, 0-day gap)	41,699	31.7	119.3	1	6	7	20	2,824
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	12.8	12.5	2	3	10	23	29
12-17 years	-	-	-	-	-	-	-	-
18-39 years	*****	41.9	158.3	1	2	5	14	2,824
40-64 years	*****	34.9	133.3	1	3	6	19	2,430
65+ years	*****	29.6	109.3	1	6	10	20	2,587

Table 8c. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, All (0-day washout, 0-day gap)	6,784,282	56.4	188.3	1	3	10	32	3,244
<2 years	*****	43.0	143.6	1	3	10	31	1,391
2-11 years	*****	39.4	145.1	1	4	10	24	2,089
12-17 years	*****	53.3	191.3	1	4	9	31	2,530
18-39 years	*****	86.4	262.1	1	4	12	41	3,239
40-64 years	*****	61.4	203.7	1	3	10	33	3,219
65+ years	*****	53.0	177.5	1	3	9	31	3,244
Ranitidine, Oral solid/liquid (183-day washout, 30-day gap)	2,337,133	191.2	309.0	31	46	81	181	3,075
<2 years	*****	243.7	404.0	31	40	68	269	1,970
2-11 years	*****	176.9	289.8	31	42	73	157	2,329
12-17 years	*****	150.3	247.7	31	42	70	137	1,857
18-39 years	*****	229.2	366.1	31	48	88	221	3,024
40-64 years	*****	192.2	314.7	31	46	80	180	3,075
65+ years	*****	187.9	301.7	31	46	82	179	3,072
Ranitidine, Injection/intravenous (183-day washout, 30-day gap)	63,567	189.9	298.9	31	41	66	187	2,983
<2 years	-	-	-	-	-	-	-	-
2-11 years	*****	78.7	40.6	40	40	75	121	121
12-17 years	*****	166.0	148.6	34	34	137	327	327
18-39 years	*****	285.6	395.7	31	53	115	336	2,983
40-64 years	*****	214.4	332.6	31	41	75	221	2,980
65+ years	*****	181.0	285.9	31	41	63	177	2,911
Ranitidine, All (183-day washout, 30-day gap)	2,426,618	195.7	316.6	31	46	82	185	3,075
<2 years	*****	243.7	404.0	31	40	68	269	1,970
2-11 years	*****	175.5	287.9	31	42	73	154	2,329
12-17 years	*****	155.7	248.6	31	42	72	140	1,857
18-39 years	*****	235.4	373.6	31	48	90	229	3,024
40-64 years	*****	197.4	323.3	31	46	81	184	3,075
65+ years	*****	192.0	308.8	31	46	82	183	3,072
Famotidine, Oral solid/liquid (183-day washout, 30-day gap)	1,100,489	199.9	326.7	31	46	81	185	3,052
<2 years	*****	115.3	100.4	37	42	85	189	254
2-11 years	*****	211.6	390.5	31	40	59	111	2,089
12-17 years	*****	188.2	332.7	31	42	72	154	2,459
18-39 years	*****	277.0	419.0	31	51	101	291	3,029
40-64 years	*****	215.0	349.9	31	47	84	201	3,045
65+ years	*****	190.2	311.2	31	45	79	176	3,052

Table 8c. Descriptive Statistics of the Length of All Gaps between Treatment Episodes in the Sentinel Distributed Database (SDD) from January 1, 2010 through December 31, 2018, in Days, by Age Group

Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Famotidine, Injection/intravenous (183-day washout, 30-day gap)	3,303	190.0	292.3	31	43	75	180	2,365
<2 years	-	-	-	-	-	-	-	-
2-11 years	-	-	-	-	-	-	-	-
12-17 years	-	-	-	-	-	-	-	-
18-39 years	*****	279.6	342.5	31	63	127	358	1,611
40-64 years	*****	197.8	291.2	31	43	82	199	2,093
65+ years	*****	178.2	285.8	31	42	69	162	2,365
Famotidine, All (183-day washout, 30-day gap)	1,106,026	200.7	327.9	31	46	81	186	3,052
<2 years	*****	115.3	100.4	37	42	85	189	254
2-11 years	*****	211.6	390.5	31	40	59	111	2,089
12-17 years	*****	188.2	332.7	31	42	72	154	2,459
18-39 years	*****	278.7	420.3	31	51	102	295	3,029
40-64 years	*****	216.0	351.4	31	47	84	202	3,045
65+ years	*****	190.8	312.2	31	45	79	176	3,052

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented

Appendix A. Dates of Available Data for DP01 as of Request Distribution Date (October 28, 2019)

DP ID	DP Start Date[1]	DP End Date[1]
DP01	1/1/2010	12/31/2018

[1]The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures and Incidence Criteria in this Request

Generic Name	Brand Name
Oral Ranitidine	
ranitidine HCl/dietary supplement no.17	Gabitidine
ranitidine HCl/dietary supplement no.8	Sentradine
ranitidine bismuth citrate	Tritec
ranitidine HCl	ranitidine HCl
ranitidine HCl	Acid Reducer (ranitidine)
ranitidine HCl	Zantac
ranitidine HCl	Zantac 150 EFFERdose
ranitidine HCl	Zantac GELdose
ranitidine HCl	Zantac 25 EFFERdose
ranitidine HCl	Wal-Zan 150
ranitidine HCl	Wal-Zan 75
ranitidine HCl	Zantac 75
ranitidine HCl	Zantac Maximum Strength
ranitidine HCl	Taladine
ranitidine HCl	Acid Control (ranitidine)
ranitidine HCl	Heartburn Relief (ranitidine)
ranitidine HCl	Deprizine
Injection/Intravenous Ranitidine	
ranitidine HCl	Zantac
ranitidine HCl	ranitidine HCl
ranitidine HCl in 0.45 % sodium chloride	Zantac in 0.45 % sod. chloride
Oral Famotidine	
famotidine/calcium carbonate/magnesium hydroxide	Pepcid Complete
famotidine/calcium carbonate/magnesium hydroxide	Dual Action Complete
famotidine/calcium carbonate/magnesium hydroxide	Complete
famotidine/calcium carbonate/magnesium hydroxide	Acid Reducer Complete (famot)
famotidine/calcium carbonate/magnesium hydroxide	Duo Fusion
famotidine/calcium carbonate/magnesium hydroxide	Tums Dual Action (famotidine)
famotidine/calcium carbonate/magnesium hydroxide	Acid Controller Complete
ibuprofen/famotidine	Duexis
famotidine	Pepcid
famotidine	Pepcid RPD
famotidine	famotidine
famotidine	Acid Reducer (famotidine)
famotidine	Acid Controller
famotidine	Heartburn Relief (famotidine)
famotidine	Pepcid AC
famotidine	Mylanta AR
famotidine	Heartburn Prevention
Injection/Intravenous Famotidine	
famotidine	famotidine
famotidine	Pepcid
famotidine in 0.9 % sodium chloride	famotidine in 0.9 % NaCl
famotidine in sodium chloride, iso-osmotic/PF	Pepcid in NaCl (iso-osm) (PF)
famotidine in sodium chloride, iso-osmotic/PF	famotidine (PF)-NaCl (iso-os)
famotidine/PF	famotidine (PF)
famotidine/PF	Pepcid (PF)

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures and Incidence Criteria in this Request

Generic Name	Brand Name
Cimetidine (All Forms)	
cimetidine	cimetidine
cimetidine	Tagamet
cimetidine	Heartburn Relief (cimetidine)
cimetidine	Tagamet HB
cimetidine	Acid Reducer (cimetidine)
cimetidine	Heartburn 200
cimetidine	Acid Relief (cimetidine)
cimetidine	Heartburn
cimetidine HCl	cimetidine HCl
cimetidine HCl	Tagamet
cimetidine HCl in 0.9 % sodium chloride	cimetidine in 0.9 % NaCl
Nizatidine (All Forms)	
nizatidine	Axid
nizatidine	nizatidine
nizatidine	Tagamet
nizatidine	Axid AR

Appendix C. List of Healthcare Common Procedure Coding System (HCPCS) codes to Define Exposures and Incidence Criteria in this Request

Code	Description	Code Type	Code Category
	Ranitidine Injection		
J2780	Injection, ranitidine hydrochloride, 25 mg	HC	Procedure
	Famotidine Injection		
S0028	Injection, famotidine, 20 mg	HC	Procedure
	Cimetidine Injection		
S0023	Injection, cimetidine hydrochloride, 300 mg	HC	Procedure

Appendix D. List of Generic and Brand Drug Names Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Proton-Pump Inhibitor (All Forms)	
omeprazole magnesium	Acid Reducer (omeprazole)
rabeprazole sodium	AcipHex
rabeprazole sodium	AcipHex Sprinkle
dexlansoprazole	Dexilant
esomeprazole magnesium/glycerin	Esomep-EZS
esomeprazole magnesium	esomeprazole magnesium
esomeprazole sodium	esomeprazole sodium
esomeprazole strontium	esomeprazole strontium
LANSOPRAZOLE	FIRST-Lansoprazole
OMEPRAZOLE	FIRST-Omeprazole
lansoprazole	Heartburn Relief 24 Hour
esomeprazole magnesium	Heartburn Treatment
lansoprazole	Heartburn Treatment 24 Hour
dexlansoprazole	Kapidex
lansoprazole	lansoprazole
esomeprazole magnesium	Nexium
esomeprazole magnesium	Nexium 24HR
esomeprazole sodium	Nexium IV
esomeprazole magnesium	Nexium Packet
omeprazole/sodium bicarbonate	OmePPi
omeprazole	omeprazole
omeprazole magnesium	omeprazole magnesium
OMEPRAZOLE	Omeprazole+SyrSpend SF Alka
omeprazole/sodium bicarbonate	omeprazole-sodium bicarbonate
pantoprazole sodium	pantoprazole
lansoprazole	Prevacid
lansoprazole	Prevacid 24Hr
lansoprazole	Prevacid IV
lansoprazole/naproxen	PREVACID NapraPAC
lansoprazole	Prevacid SoluTab
omeprazole	Prilosec
omeprazole magnesium	Prilosec
omeprazole magnesium	Prilosec OTC
pantoprazole sodium	Protonix
rabeprazole sodium	rabeprazole
omeprazole/sodium bicarbonate	Zegerid
omeprazole/sodium bicarbonate	Zegerid OTC

Appendix E. List of Healthcare Common Procedure Coding System (HCPCS) codes to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
	Proton Pump Inhibitor Injection		
S0164	Injection, pantoprazole sodium, 40 mg	HC	Procedure
C9113	Injection, pantoprazole sodium, per vial	HC	Procedure

Appendix F. Specifications Defining Parameters for this Request

The Center for Drug Evaluation and Research (CDER) has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1, to assess the use patterns of ranitidine and a comparator agent, famotidine, within the Sentinel Distributed Database (SDD).

Query period: January 1, 2010 - December 31, 2018
Coverage requirement: Medical and Drug
Pre-index enrollment requirement: Minimum required; currently equals the number of washout days (see scenarios below)
Post-index enrollment requirement: 0 days
Enrollment gap: 45 days
Age groups: 0-1, 2-11, 12-17, 18-39, 40-64, 65+ years
Stratifications: Overall, sex, and age group
Censor output categorization: N/A
Restrictions: N/A
Distribution of index-defining codes: Not requested
Envelope macro: Default (Reclassify encounters during inpatient stay as inpatient)
Freeze data: Not requested
Data Source: All Sentinel Data Partners

	Exposure													Baseline Characteristics
Scenario	Index exposure	Index exposure form	Cohort definition	Pre-index enrollment requirement	Incident exposure washout period	Incident with respect to:	Incidence evaluation	Episode gap	Episode extension	Minimum episode duration	Minimum days supplied	Maximum episode duration	Forced Days Supplied	Censor episode at evidence of:	
1	Ranitidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
2	Ranitidine	Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G

Appendix F. Specifications Defining Parameters for this Request														
3	Ranitidine	Oral solid/liquid or Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
4	Famotidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
5	Famotidine	Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
6	Famotidine	Oral solid/liquid or Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	0 days	0 days	N/A	N/A	0 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
7	Ranitidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G

Appendix F. Specifications Defining Parameters for this Request														
8	Ranitidine	Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
9	Ranitidine	Oral solid/liquid or Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
10	Famotidine	Oral solid/liquid	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G
11	Famotidine	Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	ho	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G

Appendix F. Specifications Defining Parameters for this Request															
12	Famotidine	Oral solid/liquid or Injection/ intravenous	All valid exposure episodes during query period (All cohort entry criteria apply to the first episode only.)	183 days	183 days	Any of ranitidine, famotidine, cimetidine, or nizatidine	Washout lookback period should search for evidence of days supply	30 days	0 days	1	1	N/A	N/A	Death; Query End Date; Data Partner End Date	See Appendix G

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360.

NDC codes are checked against First Data Bank's “National Drug Data File (NDDF®) Plus.”

Appendix G. Specifications Defining Baseline Characteristic Parameters in this Request

Baseline Characteristics

Baseline Characteristics	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Covariate Includes Dispensings	Number of Instances the Covariate Should be Found in Evaluation Period
OTC products	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
PPIs	Pharmacy Dispensings	N/A	Day 1	End of patients' follow-up	Evaluation period should search for only evidence of a dispensing date	1
All Other	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
AHP	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Amneal Pharmace	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Apotex Corp	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Bedford Labs	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Boehringer Cons	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Boehringer/Chat	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Chattem Cons Pr	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Covis Pharmaceu	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Covis/Teligent	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Dr.Reddy's Lab	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Glaxo Pharm	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Glaxosmithkline	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Glenmark Pharma	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1

Appendix G. Specifications Defining Baseline Characteristic Parameters in this Request

Baseline Characteristics

Baseline Characteristics	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Covariate Includes Dispensings	Number of Instances the Covariate Should be Found in Evaluation Period
Gsms, Inc.	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Hi-Tech/Akorn C	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Major Pharmaceu	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Mylan	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Mylan Instituti	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Par Pharm.	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Pfizer Cons.Hlt	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Pharmaceutical	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Precision Dose	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Ranbaxy Pharmac	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Sandoz	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Silarx/Lannett	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Strides Pharma	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Teligent Pharma	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Teva Usa	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Watson Labs	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1

Appendix G. Specifications Defining Baseline Characteristic Parameters in this Request

Baseline Characteristics

Baseline Characteristics	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Covariate Includes Dispensings	Number of Instances the Covariate Should be Found in Evaluation Period
Wockhardt Usa L	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1
Zydus Pharmaceu	Pharmacy Dispensings	N/A	Day 0	Day 0	Evaluation period should search for only evidence of a dispensing date	1