

“An update to the FDA Adverse Event Reporting System (FAERS) Public Dashboard”



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DISCLAIMER

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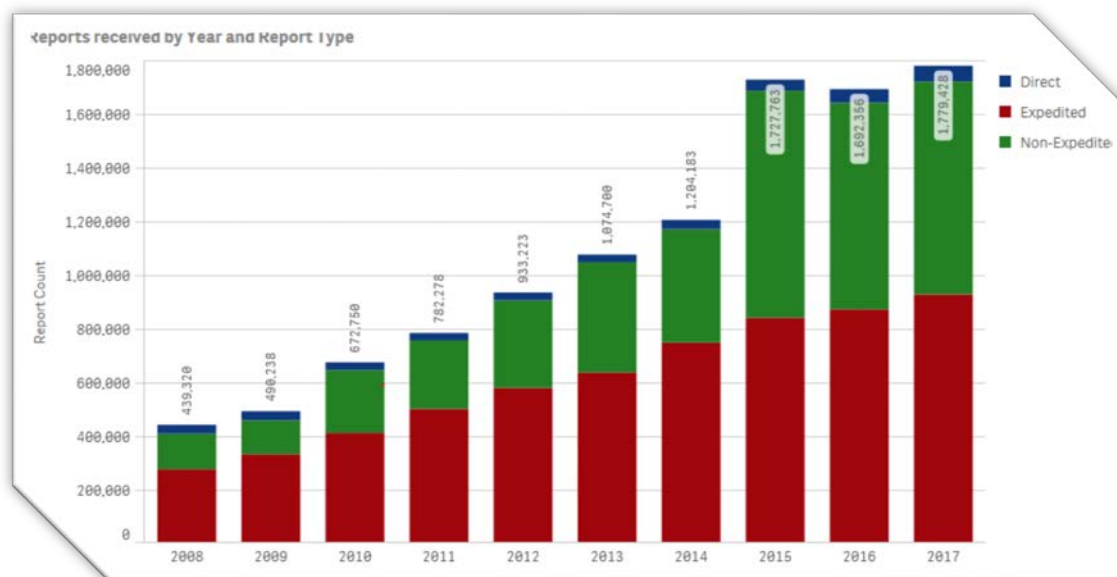
LEARNING OBJECTIVES

- ❑ Describe the FAERS public database and summarize the recent updates.
- ❑ Demonstrate how to use the FAERS public dashboard to view information on adverse event reporting metrics.
- ❑ Illustrate use of FAERS public dashboard to view adverse event information on a specific product.

BACKGROUND

The FDA Adverse Events Reporting System (FAERS) is a database that contains spontaneous adverse event reports that are submitted to FDA from the product manufacturer or directly from the consumer, healthcare professional, or other reporter. The database supports the FDA's post marketing safety surveillance program for drug and therapeutic biologic products.

The database consists of more than fifteen (15) million reports since 1969 to June 2018. Each year, FDA receives over one (1) million adverse events and medication error reports associated with the use of drug or biologic products. Existence of a report does not establish causation.



OBJECTIVE



FDA provides information to the public in an accessible and transparent manner. This new FAERS dashboard gives the public and industry a more [user friendly platform](#) for accessing FAERS reports and making adverse event data more [accessible and transparent](#).

FAERS data outlets for public:

The image displays three panels illustrating data outlets for the public. The first panel, 'Open FDA', features the 'openFDA' logo and a blue callout box labeled 'JSON File(s)'. The second panel, 'FAERS Quarterly Data Extracts (QDE)', shows a screenshot of the FAERS system interface with a blue callout box labeled 'Text/ASCII Files and XML File(s)'. The third panel, 'FAERS Public Dashboard', shows a dashboard with a bar chart and a red star labeled 'NEW', with a blue callout box labeled 'Easy Interactive Access'. The 'Open FDA' panel also includes the text 'Open FDA' below the logo.

The FAERS Public Dashboard is an interactive application, which enables the user to search for information related to adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

KEY POINTS TO CONSIDER

Data Quality

- There are many instances of duplicative reports and some reports do not contain all the necessary information.

Existence of a report does not establish causation

- There is no certainty that a suspected drug caused the adverse events.
- Adverse events may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons.
- The information in these reports reflects only the reporter's observations and opinions.

Information in reports has not been verified

- Submission of a report does not mean that the information included in it has been medically confirmed.

KEY POINTS TO CONSIDER

- ❑ **Rates of occurrence cannot be established with reports**
 - The number of adverse events should not be used to determine the likelihood of a side effect occurring.
 - Factors such as the time a product has been marketed and publicity can influence reporting.

- ❑ **Patients should talk to their doctor** before stopping or changing how they take their medications

- ❑ **Patient Outcomes received in FAERS**
 - A reported serious outcomes does not necessarily mean that the suspect product(s) named in the report was the cause of these outcomes.



FAERS data by themselves are not an indicator that the drug is causing the reported adverse events.

SPONTANEOUS REPORTS

- A communication from an individual (e.g., health care professional, consumer) to a company or regulatory authority
- Describes a suspected adverse event(s)
- Passive and voluntary reports

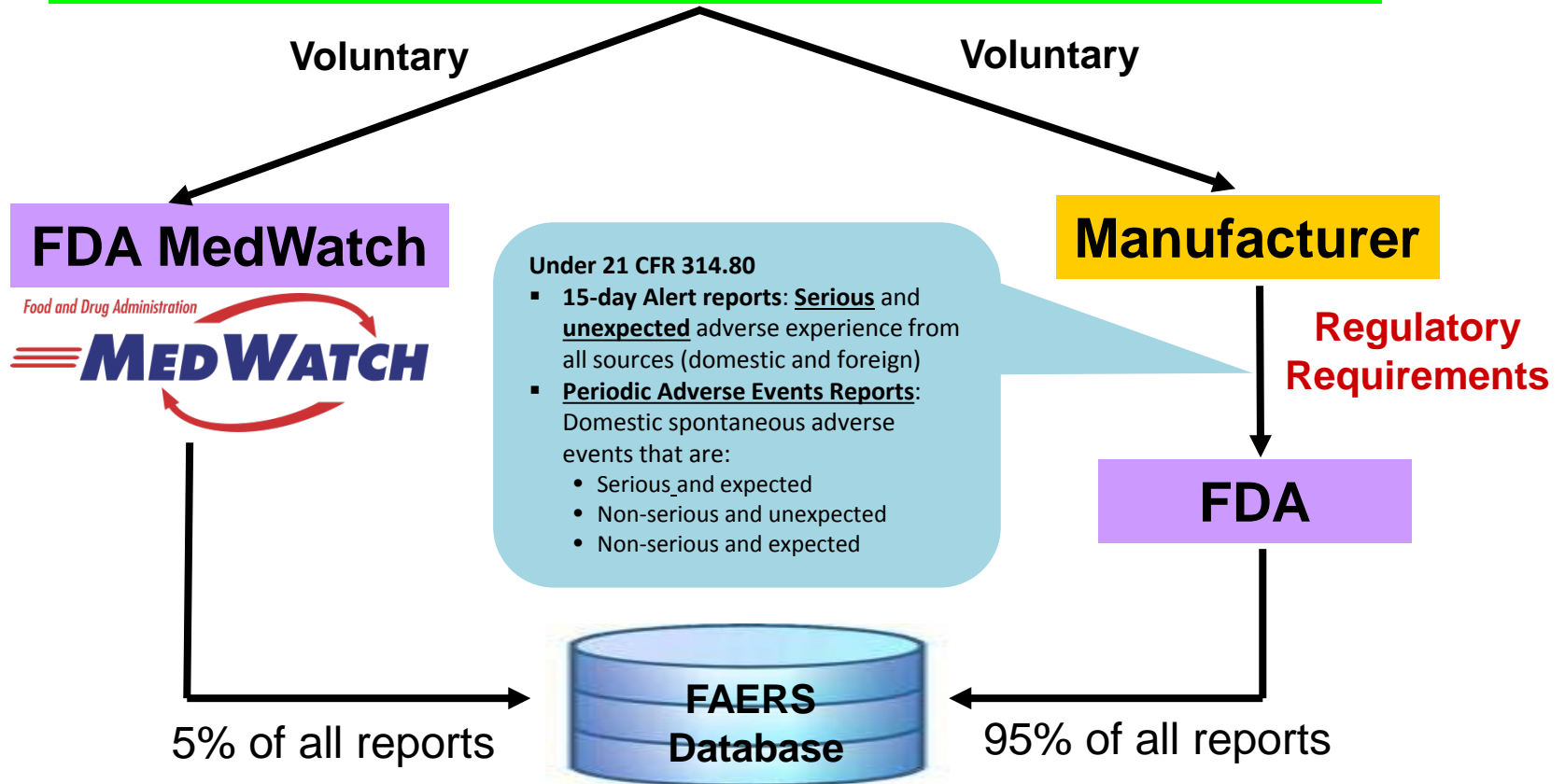
FACTORS AFFECTING REPORTING

- Media attention
- Litigation (class action lawsuits)
- Nature of the adverse event
- Type of drug product and indication
- Length of time on market
- Extent and quality of manufacturer's surveillance system
- Prescription or over-the-counter (OTC) product status
- Reporting regulations

HOW POSTMARKETING REPORTS GET TO FDA



Patients, consumer, and healthcare professionals



FAERS STRENGTHS

- ❑ Includes all U.S. marketed products
- ❑ Includes all uses
- ❑ Includes broad patient populations:
 - elderly, children, pregnant women, co-morbidities
- ❑ Especially good for events with a rare background rate
- ❑ Useful for events that occur shortly after exposure
- ❑ Detection of events not seen in clinical trials (“signal generation”)
- ❑ Identification of reporting trends, possible risk factors, at risk populations, and other clinically significant emerging safety concerns

FAERS IS LESS USEFUL FOR

- Events with high background rates
- Worsening of pre-existing disease
- Issue that goes beyond data captured from the MedWatch Form or electronic reporting
- Comparative incidence rates
- Comparing drugs in the same class
- Adverse events that could also be manifestations of the disease for which the drug is indicated



FAERS PUBLIC DASHBOARD

LAUNCH FAERS PUBLIC DASHBOARD

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>

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FDA U.S. FOOD & DRUG ADMINISTRATION
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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Drugs
Home > Drugs > Guidance, Compliance & Regulatory Information > Surveillance > FDA Adverse Event Reporting System (FAERS)

FDA Adverse Event Reporting System (FAERS)
FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files
FDA Adverse Event Reporting System (FAERS) Public Dashboard
Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)
FDA Adverse Event Reporting System (FAERS) Electronic Submissions

FDA Adverse Event Reporting System (FAERS) Public Dashboard

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

The FAERS Public Dashboard is a highly interactive web-based tool that will allow for the querying of FAERS data in a user friendly fashion. The intention of this tool is to expand access of FAERS data to the general public to search for information related to human adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

Launch the FDA Adverse Event Reporting System (FAERS) Public Dashboard

FAERS Public Dashboard

While the FAERS dashboard offers stakeholders many more ways of searching for and organizing data on adverse events reported to the FDA for many drug and biologic products, there remain limitations to the data. For example, while FAERS contains reports on a particular drug or biologic, this does not mean that the drug or biologic caused the adverse event. Importantly, the FAERS data by themselves are not an indicator of the safety profile of the drug or biologic. Some additional limitations to note include:

- Duplicate and incomplete reports are in the system:** There are many instances of duplicative reports and some reports do not contain all the necessary information.
- Existence of a report does not establish causation:** For any given report, there is no certainty that a suspected drug caused the reaction. While consumers and healthcare professionals are encouraged to report adverse events, the reaction may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons. The information in these reports reflects only the reporter's observations and opinions.
- Information in reports has not been verified:** Submission of a report does not mean that the information included in it has been medically confirmed nor it is an admission from the reporter that the drug caused or contributed the event.
- Rates of occurrence cannot be established with reports:** The information in these reports cannot be used to estimate the incidence (occurrence rates) of the reactions reported.
- Patients should talk to their doctor before stopping or changing how they take their medications.**

DISCLAIMER

Disclaimer

Each year, the FDA receives over one million adverse event and medication error reports associated with the use of drug or biologic products. The FDA uses these reports to monitor the safety of drug and biological products. The FDA Adverse Event Reporting System (FAERS) database houses reports submitted to the FDA by drug manufacturers (who are required to submit these reports to FDA) and others such as health care professionals and consumers. Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Although these reports are a valuable source of information, this surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified information. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of use. Because of this, FAERS data comprise only one part of the FDA's important post-market surveillance data and the information on this website does not confirm a causal relationship between the drug product and the reported adverse event(s).

- Consumers should not stop or change medication without first consulting with a health care professional.
- The FAERS web search feature is limited to adverse event reports between 1969 and the most recent quarter for which data are available.
- Data submitted to the FAERS system will be made available through the new querying tool on a quarterly basis.
- FAERS data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with drug products.
- Confirming whether a drug product actually caused a specific event can be difficult based solely on information provided in a given report.
- FAERS data do not represent all known safety information for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.
- Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.

Importantly, safety reports submitted to FDA do not necessarily reflect a conclusion by FDA that the information in the reports constitutes an admission that the drug caused or contributed to an adverse event. Individual FAERS reports for a given product can be requested by submitting a Freedom of Information Act (FOIA) request at:

<https://www.fda.gov/regulatoryinformation/foi/howtomakeafoiarequest/default.htm>

I have read and understand the disclaimer.

Accept

Do Not Accept

Click on the check box to acknowledge and click on "Accept" to view information on the dashboard

KEY PARTS OF DASHBOARD

Filter panel

Selected filter criteria

No selections applied

Navigation panel

Main Dashboard Page

Provides an option to search cases by adverse events or by products

View Disclaimer

Provide feedback on the dashboard

Report an adverse event via a web portal

Frequently Asked Questions

Home Search Disclaimer Site Feedback Report a Problem FAQ

Results panel

Total Reports

14,179,191

Displays total number of reports as of a date

Serious Reports (excluding death)

8,072,479

Displays counts of all serious reports (excluding death reports)

Death Reports

1,420,285

Displays counts of all death reports

Reports by Report Type

View reports by different criterias

KEY PARTS OF DASHBOARD



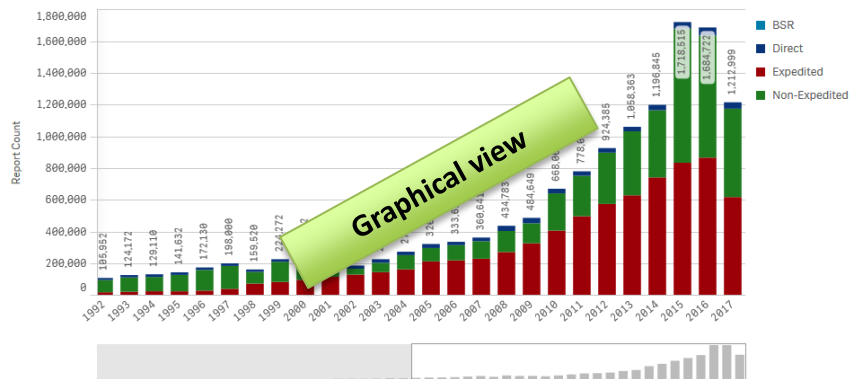
Data panel

Reports received by Year and Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	14,160,191	7,437,939		739,781	873
2017	1,212,999	615,558		40,383	-
2016	1,684,722	864,309		50,879	-
2015	1,718,515	831,111		41,539	-
2014	1,196,845	585,052		423,150	-
2013	1,058,363	493,368		28,303	-
2012	924,385	323,059		28,866	-
2011	778,815	294,961		27,995	-
2010	668,019	404,586		234,578	-
2009	484,649	324,421		126,138	-
2008	434,783	269,298		132,659	-
2007	360,641	227,294		110,389	-
2006	333,629	217,213		95,525	-
2005	320,616	210,363		84,472	6
2004	271,418	160,008		89,833	5
2003	234,344	143,750		73,970	14

Tabular view

Reports received by Year and Report Type



Graphical view

Page help panel

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

- Direct Reports are voluntarily submitted directly to FDA through the MedWatch program by consumers and healthcare professionals.
- Mandatory Reports are submitted by manufacturers and are categorized as:
 - Expedited reports that contain at least one adverse event that is not currently described in the product labeling and for which the patient outcome is serious, or
 - Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.

Describes the details of data displayed on the page

MAIN DASHBOARD PAGE



Main Dashboard Page

Selected filter criteria

Provides an option to search cases by adverse events or products

Provide feedback on the dashboard

Report an adverse event via a web portal

Frequently Asked Questions

Displays counts of all death reports

View Disclaimer

Disclaimer Site Feedback Report a Problem FAQ



Total Reports
15,949,618

Displays total number of reports as of a date

Serious Reports (excluding death)
8,992,563

Displays counts of all serious reports (excluding death reports)

Death Reports
1,606,809

View reports by different criteria

Reports by Report Type

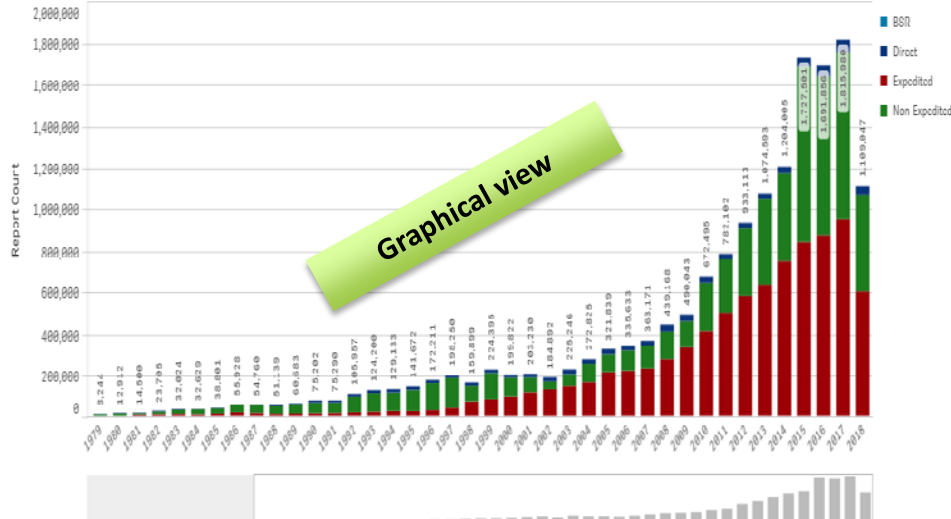
Since 1968 Last 10 Years

Reports received by Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
Total Reports	15,949,618	8,431,523	6,713,246	883,873	876
2018	1,189,847	598,952	469,288	48,845	-
2017	1,815,980	958,429	883,524	62,827	-
2016	1,691,856	869,858	771,005	58,993	-
2015	1,727,581	-	846,788	41,659	-
2014	1,204,085	-	423,741	34,233	-
2013	1,874,593	634,793	411,418	28,398	-
2012	933,111	577,588	326,584	29,821	-
2011	782,182	498,828	255,231	28,843	-
2010	672,495	498,879	234,672	28,944	-
2009	498,843	329,785	126,172	34,106	-

Tabular view

Reports received by Report Type



Graphical view

Describes the details of data displayed on the page

Data as of June 30, 2018

- This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.
- Direct Reports are voluntarily submitted directly to FDA through the MedWatch program by consumers and healthcare professionals.
 - Mandatory Reports are submitted by manufacturers and are categorized as:
 - Expedited reports that contain at least one adverse event that is not currently described in the product labeling and for which the patient outcome is serious, or
 - Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.
 - BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.



MAIN DASHBOARD

REPORTS BY REPORT TYPE

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by report type

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard



Home Search

Disclaimer Site Feedback Report a Problem FAQ

Total Reports
15,384,274

Serious Reports (excluding death)
8,706,271

Death Reports
1,550,815

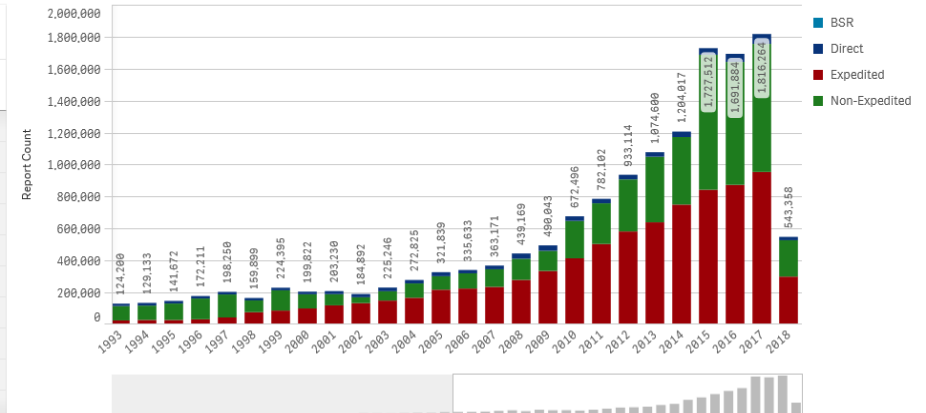
Reports by Report Type

Since 1968 Last 10 Years

Reports received by Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
2018	543,358	294,104	228,248	21,006	-
2017	1,816,264	950,689	803,548	62,027	-
2016	1,691,884	869,879	771,012	50,993	-
2015	1,727,512	839,152	846,701	41,659	-
2014	1,204,017	746,043	423,742	34,232	-
2013	1,074,600	634,800	411,410	28,390	-
2012	933,114	577,508	326,585	29,021	-
2011	782,102	498,828	255,231	28,043	-
2010	672,496	408,880	234,672	28,944	-
2009	490,043	329,705	126,172	34,166	-

Reports received by Report Type



Data as of March 31, 2018

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

- Direct Reports are voluntarily submitted directly to FDA through the MedWatch program by consumers and healthcare professionals.
- Mandatory Reports are submitted by manufacturers and are categorized as:
 - Expedited reports that contain at least one adverse event that is not currently described in the product labeling and for which the patient outcome is serious, or
 - Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.
- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.



MAIN DASHBOARD

REPORTS BY REPORTER

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by type of reporter

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard



Home Search Disclaimer Site Feedback Report a Problem FAQ

Total Reports 15,384,274

Serious Reports (excluding death) 8,706,271

Death Reports 1,550,815

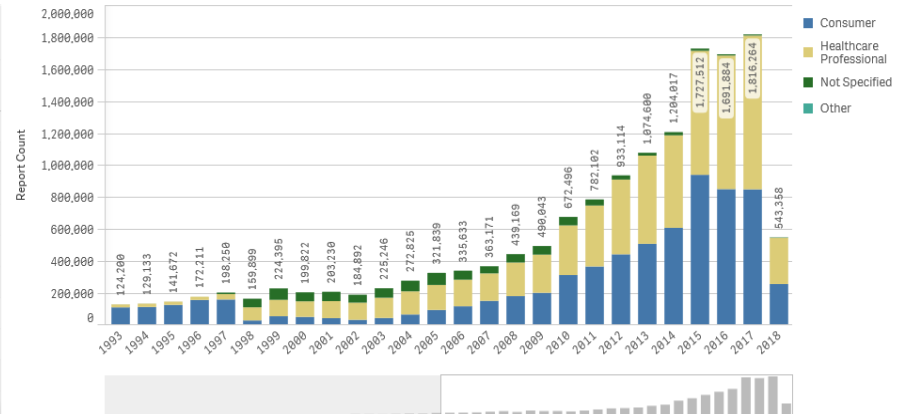
Reports by Reporter

Since 1968 Last 10 Years

Reports received by Reporter

Year	Reporter	Total Reports	Consumer	Healthcare Professional	Not Specified	Other
Total Reports		15,384,274	7,352,806	7,131,701	899,760	7
2018		543,358	251,763	288,787	2,808	-
2017		1,816,264	845,529	963,346	7,389	-
2016		1,691,884	846,736	837,194	7,954	-
2015		1,727,512	936,173	777,394	13,945	-
2014		1,204,017	604,076	579,925	20,016	-
2013		1,074,600	503,889	552,731	17,979	1
2012		933,114	438,112	468,424	26,572	6
2011		782,102	361,858	382,069	38,175	-
2010		672,496	308,103	311,255	53,138	-

Reports received by Reporter



Data as of March 31, 2018

This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Other" for all other Reporters who are not documented as Healthcare Professionals or Consumers, and "Not Specified" where the occupation of the Reporter was not provided.

MAIN DASHBOARD

REPORTS BY REPORTER REGION



Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic based on the country where the event occurred.

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard



Home Search Disclaimer Site Feedback Report a Problem FAQ

Total Reports
15,384,274

Serious Reports (excluding death)
8,706,271

Death Reports
1,550,815

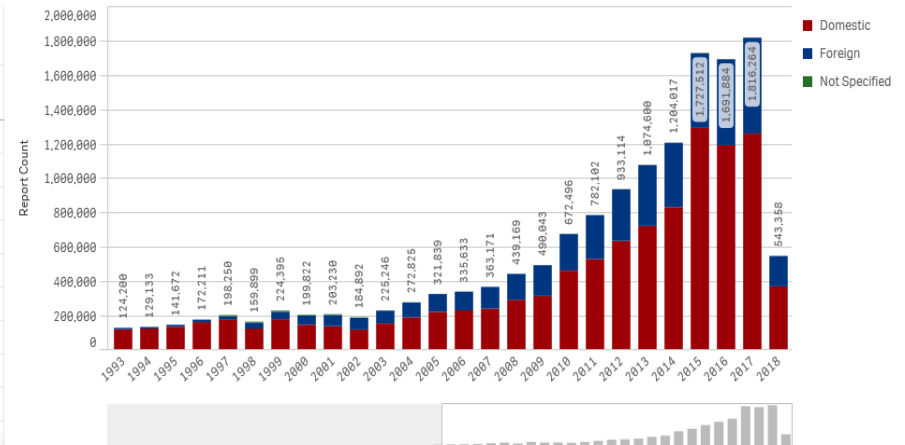
Reports by Reporter Region

Since 1968 Last 10 Years

Reports received by Reporter Region

Year	Reporter Region	Total Reports	Domestic	Foreign	Not Specified
Total Reports		15,384,274	10,945,583	4,396,601	42,090
2018		543,358	365,367	177,986	5
2017		1,816,264	1,257,163	559,047	54
2016		1,691,884	1,189,110	500,881	1,893
2015		1,727,512	1,290,145	435,422	1,945
2014		1,204,017	828,055	375,016	946
2013		1,074,600	717,850	355,946	804
2012		933,114	631,137	300,649	1,328
2011		782,102	524,771	256,001	1,330
2010		672,496	458,020	213,589	887

Reports received by Reporter Region



Data as of March 31, 2018
 This page displays the report counts based on the country where the event occurred or the country of the Reporter if event country information is not available. "Domestic" means that the country where the event occurred or the Reporter's country is the United States. "Foreign" means that the country where the event occurred or the country of the Reporter is outside the United States. "Not Specified" means that there was no data in the report that documented the geographic region of the event or the reporter.



MAIN DASHBOARD

REPORTS BY REPORT SERIOUSNESS

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by outcome of the patient as defined in regulations (21CFR 310.305, 314.80, 314.98, 600.80) and FDA MedWatch forms (3500 and 3500B)

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard U.S. FOOD & DRUG ADMINISTRATION

Home Search Disclaimer Site Feedback Report a Problem FAQ

Total Reports
 15,384,274

Serious Reports (excluding death)
 8,706,271

Death Reports
 1,550,815

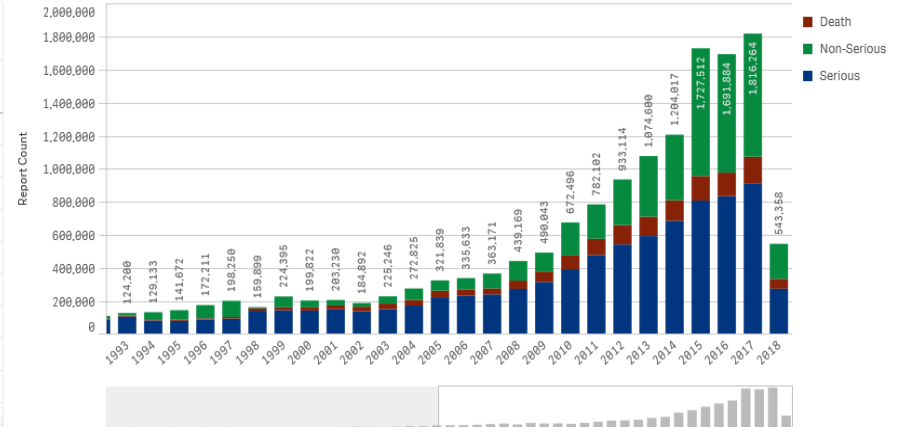
Reports by Report Seriousness

Since 1968 Last 10 Years

Reports received by Report Seriousness

Year	Total Reports	Serious	Death	Non-Serious
Total Reports	15,384,274	8,706,271	1,550,815	5,127,188
2018	543,358	271,852	59,233	212,273
2017	1,816,264	906,773	164,154	745,337
2016	1,691,884	832,211	142,127	717,546
2015	1,727,512	805,176	148,769	773,567
2014	1,204,017	682,901	124,749	396,367
2013	1,074,600	590,574	116,824	367,202
2012	933,114	539,442	117,529	276,143
2011	782,102	474,941	98,942	208,219
2010	672,496	389,687	82,955	199,854

Reports received by Report Seriousness



Data as of March 31, 2018

This page displays the report counts by the outcome of the patient as defined in U.S. reporting regulations (21 CFR 310.305, 314.80, 314.98, 600.80) and Forms FDA 3500 and 3500A. "Serious" indicates that one or more of the following outcomes, excluding death, were documented in the report: hospitalization, life-threatening, disability, congenital anomaly, required intervention, and/or other serious outcome. "Death" indicates that the outcome was documented as Death. "Non-Serious" is used for outcomes which were not documented as Serious or Death.

SEARCH BY PRODUCTS OR REACTION TERMS

SEARCH BY PRODUCTS



Click here to search

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Search Disclaimer Site Feedback Report a Problem FAQ

Total Reports
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Death Reports
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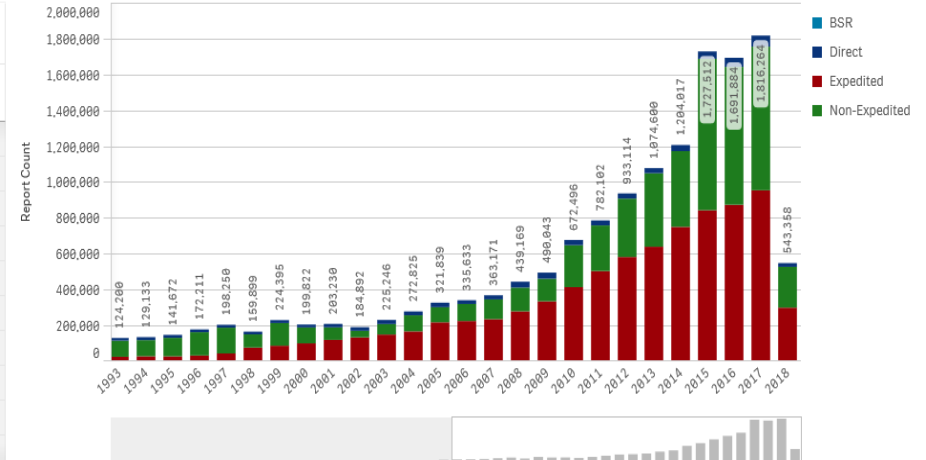
Reports by Report Type

Since 1968 Last 10 Years

Reports received by Report Type

Year	Total Reports	Expedited	Non-Expedited	Direct	BSR
2018	543,358	294,104	228,248	21,006	-
2017	1,816,264	950,689	803,548	62,027	-
2016	1,691,884	869,879	771,012	50,993	-
2015	1,727,512	839,152	846,701	41,659	-
2014	1,204,017	746,043	423,742	34,232	-
2013	1,074,600	634,800	411,410	28,390	-
2012	933,114	577,508	326,585	29,021	-
2011	782,102	498,828	255,231	28,043	-
2010	672,496	408,880	234,672	28,944	-
2009	490,043	329,705	126,172	34,166	-

Reports received by Report Type



Data as of March 31, 2018

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- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.

SEARCH BY PRODUCTS



No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Search

Disclaimer Site Feedback Report a Problem FAQ

Search by Product Search by Reaction Term *(Up to 5 products can be selected)*

Go

Search by product (brand name) or active ingredient (generic name). This field provides a smart search capability

Search by reaction term. This field provides a smart search capability

SEARCH FOR PRODUCTS



Navigation bar with "Home", "Search", "Disclaimer", "Site Feedback", "Report a Problem", and "FAQ".

Field to search by both brand name and generic name products. Typing three letters provides all match texts highlighted in yellow.

Select "Amlodipine Besylate And Valsartan"

Search interface showing a dropdown menu with search results for "aml".

Search Method	Product Name	Label
Search by Product	Amlodipine	P
Search by Product	Amlodipine And Atorvastatin	P
Search by Product	Amlodipine And Olmesartan Medoxomil	P
Search by Product	Amlodipine And Valsartan	P
Search by Product	Amlodipine Besylate And Benazepril Hydrochloride	P
Search by Product	Amlodipine Besylate And Valsartan	P
Search by Product	Amlodipine Besylate/Atorvastatin Calcium	P
Search by Product	Amlodipine Besylate\Atenolol	G
Search by Product	Amlodipine Besylate\Atorvastatin	G
Search by Product	Amlodipine Besylate\Atorvastatin Calcium	G
Search by Product	Amlodipine Besylate\Azilsartan	G
Search by Product	Amlodipine Besylate\Benazepril Hydrochloride	G
Search by Product	Amlodipine Besylate\Candesartan Cilexetil	G
Selected Products (2 of 5 allowed products selected)	Amlodipine Besylate	G
Selected Products (2 of 5 allowed products selected)	Amlodipine Besylate And Atorvastatin Calcium	P

P (in green color) – Brand Name of the product

G (in orange color) – Generic Name of the product

Selected Products for search (up to 5 allowed)

Go

Click on "Go" to run the search

SEARCH PRODUCT RESULT



Search Term: 2 of 24586

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home | Demographics | Reaction Group | Reaction | Listing of Cases | Disclaimer | Site Feedback | Report a Problem | FAQ

Search by Product

AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases: 50,549

Serious Cases (including deaths): 43,909

Death Cases: 7,670

Case Count by Received Year

Year	Number of Cases	Percentage
2018	1,707	3.38%
2017	4,886	9.67%
2016	4,621	7.95%
2015	3,723	7.37%
2014	3,345	6.62%
2013	3,531	6.99%
2012	2,576	5.10%
2011	2,376	4.70%
2010	2,334	4.62%
2009	1,336	2.64%
2008	968	1.91%
2007	1,026	2.03%
2006	931	1.84%
Totals	50,549	100.00%

Case Count by Received Year (Bar Chart)

- Cases by Received Year
- Cases by Reaction
- Cases by Product Name
- Cases by Generic Name
- Cases by Age Group
- Cases by Sex
- Cases by Reporter Type

Data as of March 31, 2018
This page displays the number of cases identified for the product/reaction term of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

Filter applied for the selected product

Total number of latest version of the reports listed

Selected products displayed

List of reports available

DEMOGRAPHICS



Filters applied for years

Drag the mouse to select years or by individual clicks

Search Term: 2 of 24506 | Received Year: 6 of 51

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases: 22,082

Serious Cases (including deaths): 17,750

Death Cases: 3,803

Case Count by Received Year

Category	Number of Cases	Percentage
2017	4,886	22.13%
2016	4,021	18.21%
2015	3,723	16.86%
2014	3,345	15.15%
2013	3,531	15.99%
2012	2,576	11.67%
Totals	22,082	100.00%

Year	Number of Cases
2018	1,707
2017	4,886
2016	4,021
2015	3,723
2014	3,345
2013	3,531
2012	2,576
2011	2,376
2010	2,334
2009	1,336
2008	968
2007	1,026
2006	931

Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Search Term: 2 of 24506 | Received Year: 6 of 51

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 22,082

Serious Cases (including deaths) 17,759

Death Cases 3,803

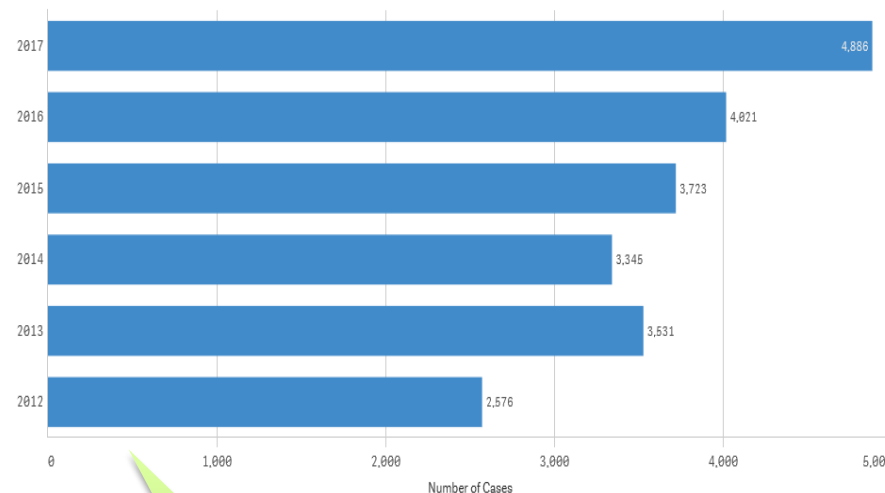
Cases by Received Year

Case Count by Received Year

Category	Number of Cases	Percentage
2017	4,886	22.13%
2016	4,021	18.21%
2015	3,723	16.86%
2014	3,345	15.15%
2013	3,531	15.99%
2012	2,576	11.67%
Totals	22,082	100.00%

Case by years - tabular view

Case Count by Received Year



Case by years - graphical view

Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

DEMOGRAPHICS



Search Term: 2 of 24506 | Received Year: 6 of 51

Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017: 22,082

Serious Cases (including deaths): 17,759

Death Cases: 3,803

Cases by Reactions

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Search by Product

Total Cases: 22,082

Serious Cases (including deaths): 17,759

Death Cases: 3,803

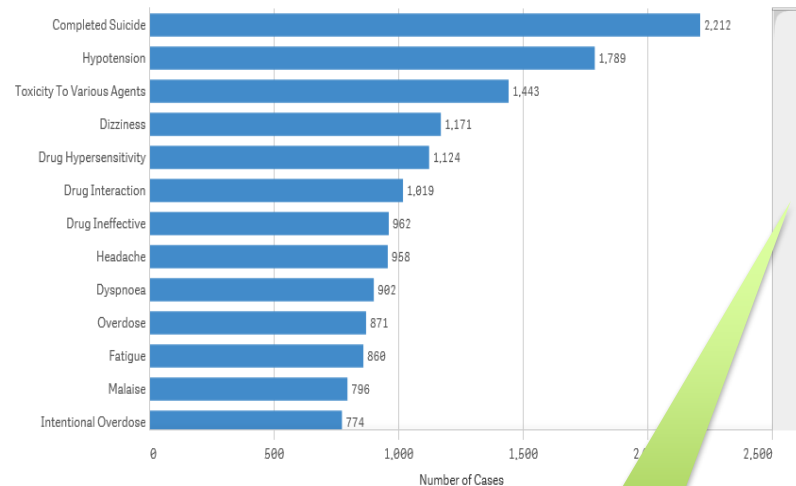
Cases by Reaction

Case Count by Reaction

Category	Number of Cases	Percentage
Completed Suicide	2,212	10.02%
Hypotension	1,789	8.10%
Toxicity To Various Agents	1,443	6.53%
Dizziness	1,171	5.30%
Drug Hypersensitivity	1,124	5.09%
Drug Interaction	1,019	4.61%
Drug Ineffective	962	4.36%
Headache	958	4.34%
Dyspnoea	902	4.08%
Overdose	871	3.94%
Fatigue	860	3.89%
Malaise	796	3.60%
Intentional Overdose	774	3.51%
Totals	22,082	100.00%

Reactions listed in descending order

Case Count by Reaction



Scrollbar to view all reactions

Data as of March 31, 2018

This page displays the number of cases for a symptom, sign, disease, diagnosis,

"Reaction". "Reaction" is the suspected side effect (also known as adverse event or adverse drug reaction) reported by the reporter and is based on the MedDRA dictionary Preferred Term (PT). A "Reaction" is a unique medical concept (e.g., allergic reaction, dizziness, headache, etc.). A case may contain more than one "Reaction".

DEMOGRAPHICS



Search Term: 2 of 24686 | Received Year: 6 of 51

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases
22,082

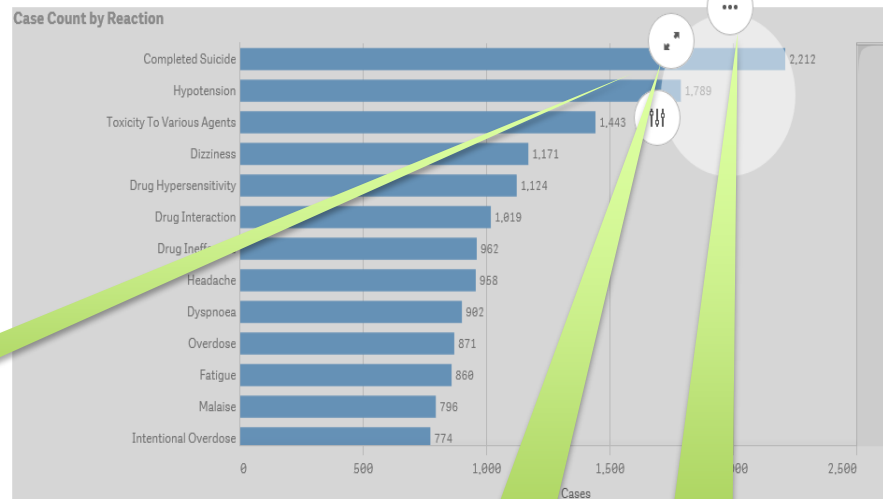
Serious Cases (including deaths)
17,759

Death Cases
3,803

Case Count by Reaction

Category	Number of Cases	Percentage
Completed Suicide	2,212	10.02%
Hypotension	1,789	8.10%
Toxicity To Various Agents	1,443	6.53%
Dizziness	1,171	5.30%
Drug Hypersensitivity	1,124	5.09%
Drug Interaction	1,019	4.61%
Drug Ineffective	962	4.36%
Headache	958	4.34%
Dyspnoea	902	4.08%
Overdose	871	3.94%
Fatigue	860	3.89%
Malaise	796	
Intentional Overdose	774	
Totals	22,082	

Case Count by Reaction



Right click on chart or table for Additional Options

Click to expand the view

Click to Export

Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Reaction". "Reaction" is the suspected side effect (also known as adverse event or adverse drug reaction) reported by the reporter and is based on the MedDRA Preferred Term (PT). A PT is a unique medical concept for a symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medical procedure, etc. A case may contain more than one "Reaction".

DEMOGRAPHICS



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Search by product

AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases: 22,082

Serious Cases (including deaths): 17,759

Death Cases: 3,803

Cases by Generic Name

Years filter applied from 2012 to 2017

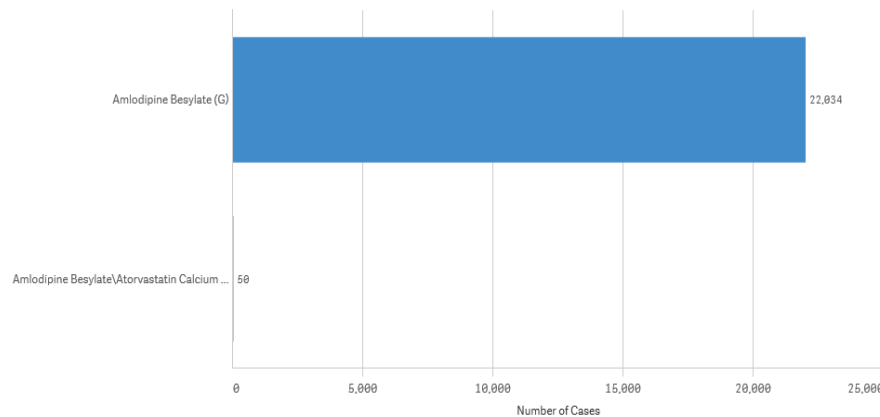
Total number of cases for the 2012 to 2017

Cases by Generic Name

Case Count by Generic Name

Category	Number of Cases	Percentage
Amlodipine Besylate (G)	22,034	99.78%
Amlodipine Besylate\Atorvastatin Calcium (G)	50	0.23%
Totals	22,082	100.00%

Case Count by Generic Name



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Generic Name". "Generic Name" is the reported generic name of the product.

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases: 22,082

Serious Cases (including deaths): 17,759

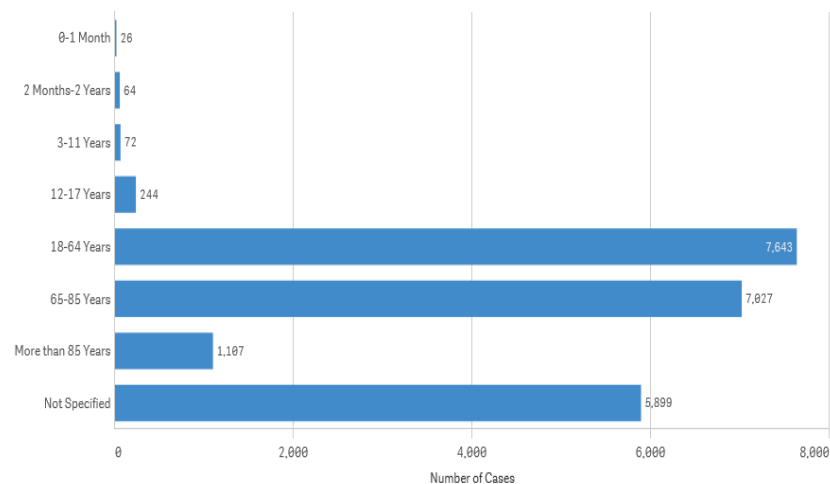
Death Cases: 3,803

Cases by Age Group

Case Count by Age Group

Category	Q	Number of Cases	Percentage
0-1 Month		26	0.12%
2 Months-2 Years		64	0.29%
3-11 Years		72	0.33%
12-17 Years		244	1.10%
18-64 Years		7,643	34.61%
65-85 Years		7,027	31.82%
More than 85 Years		1,107	5.01%
Not Specified		5,899	26.71%
Totals		22,082	100.00%

Case Count by Age Group



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by the reported age of the patient. "Not Specified" indicates the patient's age was not reported.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Sex

Search Term: 2 of 24586 | Received Year: 6 of 51

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Search by product

AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases: 22,082

Serious Cases (including deaths): 17,759

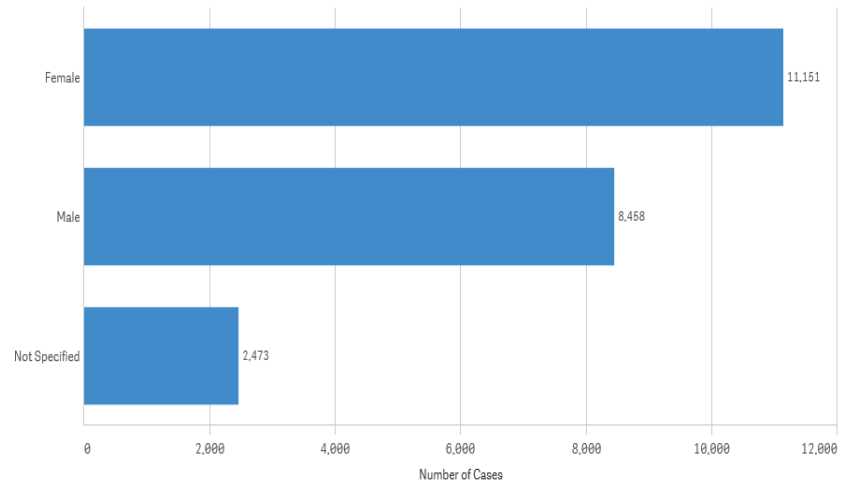
Death Cases: 3,803

Cases by Sex

Case Count by Sex

Category	Number of Cases	Percentage
Female	11,151	50.50%
Male	8,458	38.30%
Not Specified	2,473	11.20%
Totals	22,082	100.00%

Case Count by Sex



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by sex. "Not Specified" indicates the patient's sex was not reported.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reporter Type

Search Term: 2 of 24506 | Received Year: 6 of 51

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Search product

AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases: 22,082

Serious Cases (including deaths): 17,759

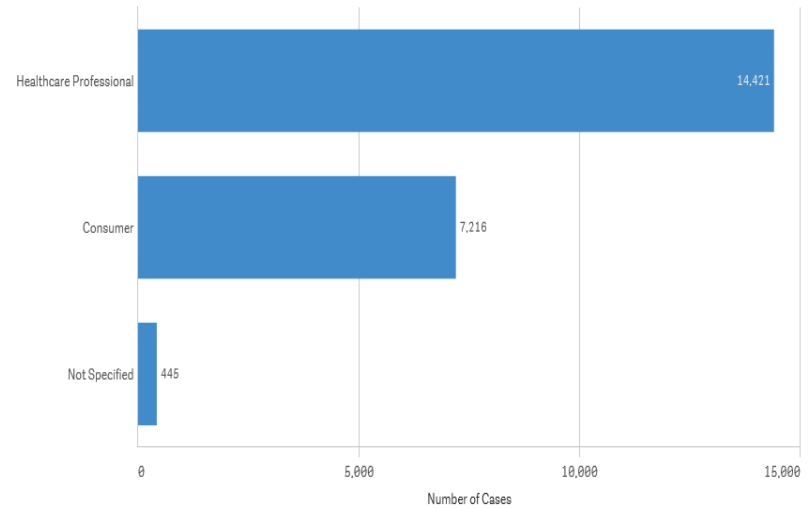
Death Cases: 3,803

Cases by Reporter Type

Case Count by Reporter

Category	Number of Cases	Percentage
Healthcare Professional	14,421	65.31%
Consumer	7,216	32.68%
Not Specified	445	2.02%
Totals	22,082	100.00%

Case Count by Reporter



Data as of March 31, 2018

This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Other" for all other Reporters who are not documented as Healthcare Professionals or Consumers, and "Not Specified" where the occupation of the Reporter was not provided.

DEMOGRAPHICS



Reporter type filter
"Healthcare Professional" applied

Total number of cases based on applied filter

Cases by Reporter Type

Search Term: 2 of 24506
Received Year: 6 of 51
Reporter Type: Healthcare Profe...

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

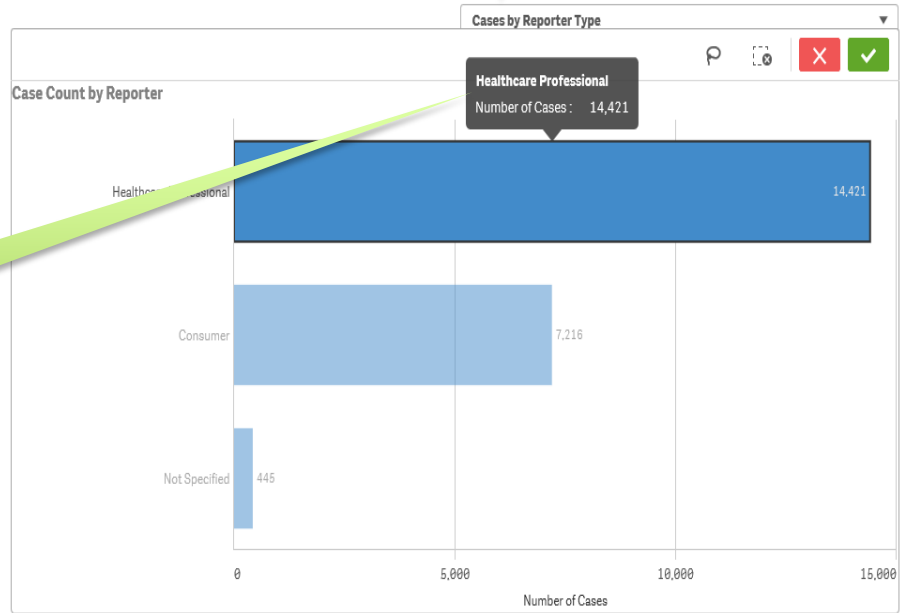
Total Cases
14,421

Serious Cases (including deaths)
12,842

Death Cases
3,366

Case Count by Reporter

Category	Number of Cases	Percentage
Healthcare Professional	14,421	100.00%
Totals	14,421	100.00%



Click to view information

Data as of March 31, 2018

This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Other" for all other Reporters who are not documented as Healthcare Professionals or Consumers, and "Not Specified" where the occupation of the Reporter was not provided.

REACTION GROUP



Search Term: 2 of 24506
Received Year: 6 of 51
Reporter Type: Healthcare Profe...
Age Group: 2 of 8

Age group filter applied

Total number of cases based on applied filter

Cases by Age Group

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases
5,929

Serious Cases (including deaths)
5,519

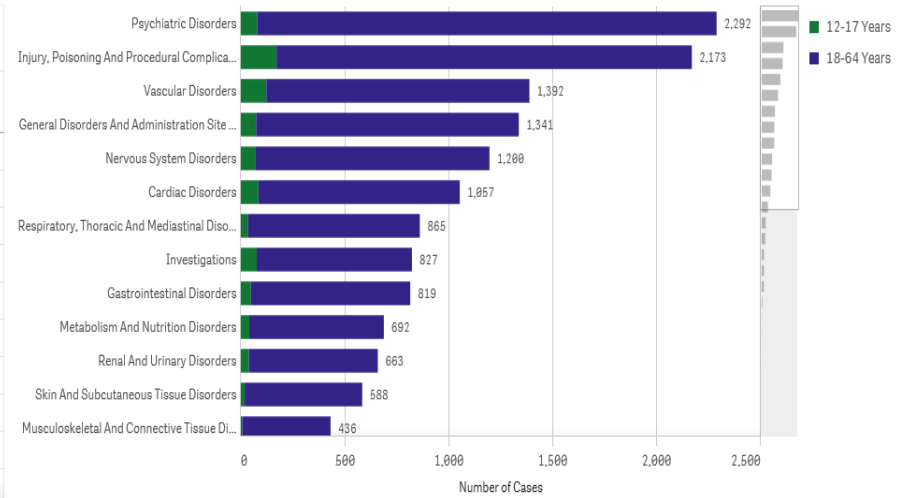
Death Cases
1,999

Cases by Age Group

Reaction Groups & Age Group

Reaction Group	Number of Cases	Age Group	
		12-17 Years	18-64 Years
Total Cases	5,929	233	5,696
Psychiatric Disorders	2,292	83	2,209
Injury, Poisoning And Procedural Complications	2,173	176	1,997
Vascular Disorders	1,392	127	1,265
General Disorders And Administration Site Conditions	1,341	78	1,263
Nervous System Disorders	1,200	76	1,124
Cardiac Disorders	1,057	89	968
Respiratory, Thoracic And Mediastinal Disorders	865	38	827
Investigations	827	81	746
Gastrointestinal Disorders	819	53	766

Reaction Groups & Age Group



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Sex

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases **5,929**

Serious Cases (including deaths) **5,519**

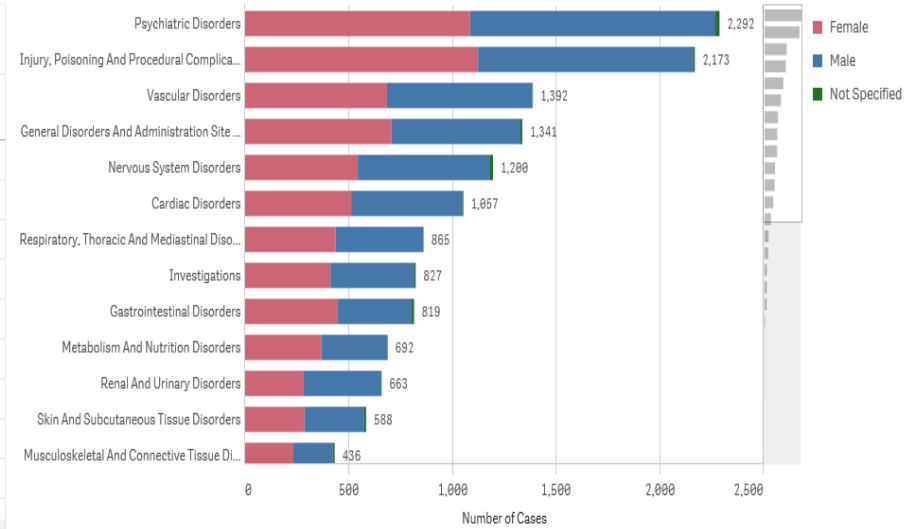
Death Cases **1,999**

Cases by Sex

Reaction Groups & Sex

Reaction Group	Number of Cases	Female	Male	Not Specified
Total Cases	5,929	2,889	2,975	65
Psychiatric Disorders	2,292	1,089	1,183	20
Injury, Poisoning And Procedural Complications	2,173	1,128	1,036	9
Vascular Disorders	1,392	689	700	3
General Disorders And Administration Site Conditions	1,341	710	622	9
Nervous System Disorders	1,200	548	638	14
Cardiac Disorders	1,057	516	537	4
Respiratory, Thoracic And Mediastinal Disorders	865	441	422	2
Investigations	827	416	405	6
Gastrointestinal Disorders	819	452	355	12

Reaction Groups & Sex



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Reaction group" and sex. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". "Not Specified" indicates the patient's sex was not reported.

REACTION GROUP



Age group filter applied

Additional filter capabilities for Reporter Type

Cases by Reporter Type

FDA Adverse Events Reporting System

Search Term: 2 of 24586 | Received Year: 6 of 51 | Reporter Type: Healthcare Professional | Age Group: 2 of 8

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AMLODIPINE BESYLATE (G); AMLODIPINE (G); ATORVASTATIN CALCIUM (P)

Total Cases: 5,929 | Serious Cases (including deaths): 5,519 | Death Cases: 1,999

Cases by Reporter Type

Reaction Groups & Reporter Type

Reaction Group	Number of Cases	Healthcare Professional
Total Cases	5,929	5,929
Psychiatric Disorders	2,292	2,292
Injury, Poisoning And Procedural Complications	2,173	2,173
Vascular Disorders	1,392	1,392
General Disorders And Administration Site Conditions	1,341	1,341
Nervous System Disorders	1,200	1,200
Cardiac Disorders	1,057	1,057
Respiratory, Thoracic And Mediastinal Disorders	865	865
Investigations	827	827
Gastrointestinal Disorders	819	819

Reaction Groups & Reporter Type

Reaction Group	Number of Cases
Psychiatric Disorders	2,292
Injury, Poisoning And Procedural Complications	2,173
Vascular Disorders	1,392
General Disorders And Administration Site Conditions	1,341
Nervous System Disorders	1,200
Cardiac Disorders	1,057
Respiratory, Thoracic And Mediastinal Disorders	865
Investigations	827
Gastrointestinal Disorders	819
Metabolism And Nutrition Disorders	692
Renal And Urinary Disorders	663
Skin And Subcutaneous Tissue Disorders	588
Musculoskeletal And Connective Tissue Disorders	436

Data as of March 31, 2018

This page displays the number of cases identified in the FAERS database for the product/reaction term of interest by "Reaction Group" and Reporter occupation. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group", may not provide information on the reporter and may contain more than one reporter.

REACTION GROUP



Age group filter applied | Total number of cases based on applied filter | Cases by Reporter Region

Search Term: 2 of 24506 | Received Year: 6 of 51 | Reporter Type: Healthcare Profe... | Age Group: 2 of 8

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

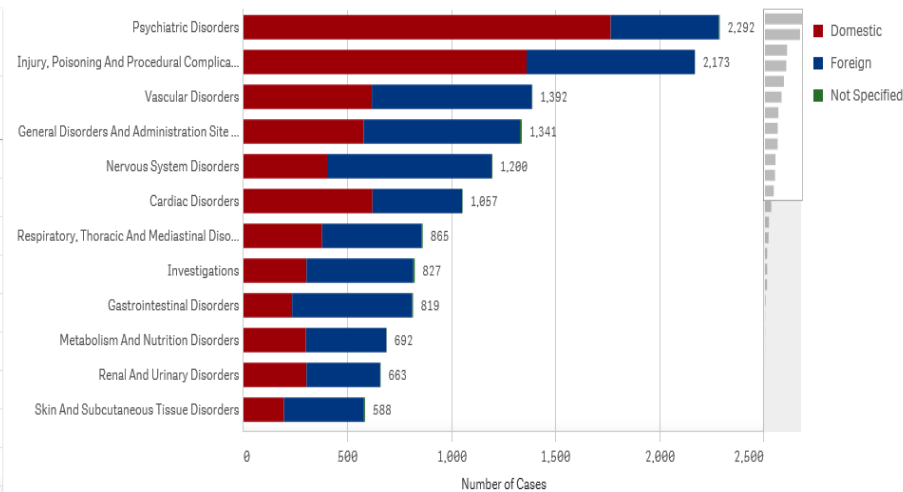
Total Cases: 5,929 | Serious Cases (including deaths): 5,519 | Death Cases: 1,999

Cases by Reporter Region

Reaction Groups & Reporter Region

Reaction Group	Reporter Region	Number of Cases	Domestic	Foreign	Not Specified
Total Cases		5,929	3,158	2,754	17
Psychiatric Disorders		2,292	1,768	520	4
Injury, Poisoning And Procedural Complications		2,173	1,364	808	1
Vascular Disorders		1,392	621	769	2
General Disorders And Administration Site Conditions		1,341	581	751	9
Nervous System Disorders		1,200	406	789	5
Cardiac Disorders		1,057	624	431	2
Respiratory, Thoracic And Mediastinal Disorders		865	382	479	4
Investigations		827	307	513	7

Reaction Groups & Reporter Region



Data as of March 31, 2018

This page displays the number of cases identified in the FAERS database for the product/reaction term of interest by "Reaction Group" and region. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". Region indicates the country where the event occurred or the country of the Reporter if event country information is not available. "Domestic" means that the country where event occurred or reporter's country is the United States. "Foreign" means that the country where the event occurred or the country of the Reporter is outside the United States. "Not Specified" means that there was no data in the report that documented the geographic region of the event or the Reporter.

REACTION



Search Term: 2 of 24506
Received Year: 6 of 51
Reporter Type: Healthcare Profe... 2 of 8
Age Group: 2 of 8
Country: Domestic
Reaction Group: Vascular Disorders

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 621

Serious Cases (including deaths) 597

Death Cases 67

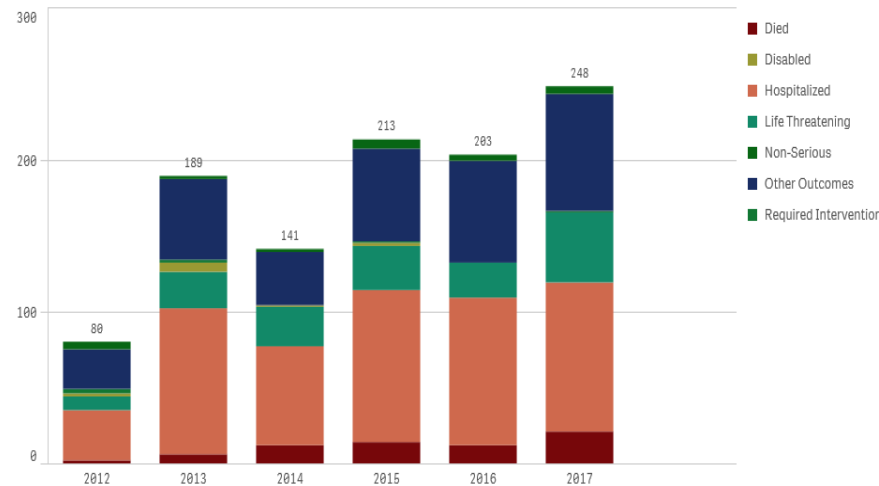
Received Year vs Outcome

Total number of cases based on applied filter

Reaction Group and Reaction

Reaction Group	Reaction	Number of Cases
Total Cases		621
Vascular Disorders		
	Number of Cases	621
	Hypotension	363
	Shock	203
	Hypertension	37
	Haemodynamic Instability	19
	Circulatory Collapse	16
	Blood Pressure Inadequately Controlled	15
	Orthostatic Hypotension	13
	Hypertensive Crisis	12

Outcome counts by Received Year



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Reaction Group", "Reaction", patient age and sex, and report outcome. A case may describe one or more "Reaction Group", "Reaction", or outcome. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". "Reaction" corresponds to the suspected reaction reported by the Reporter. The "Reaction" is based on the MedDRA dictionary Preferred Term (PT). Including one or more of these outcomes or reported reactions in a report does not necessarily mean that the suspect product of interest was the cause of the reported outcomes or reactions. A case may have one or more reported outcomes.

REACTION



Search Term 2 of 24586
Received Year 6 of 51
Reporter Type Healthcare Profe...
Age Group 2 of 8
Country Domestic
Reaction Group Vascular Disorders

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases **621**

Serious Cases (including deaths) **597**

Death Cases **67**

Age Group vs Sex ▼

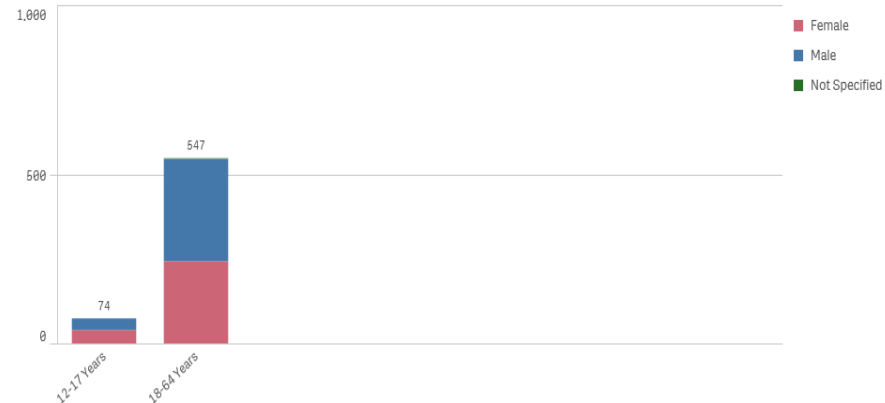
Total number of cases based on applied filter

Reaction Group and Reaction

Reaction Group Reaction

Total Cases		Number of Cases
Total Cases		621
[-] Vascular Disorders	Number of Cases	621
	Hypotension	363
	Shock	203
	Hypertension	37
	Haemodynamic Instability	19
	Circulatory Collapse	16
	Blood Pressure Inadequately Controlled	15
	Orthostatic Hypotension	13
	Hypertensive Crisis	12

Case counts by Age Group and Sex



Cases by Age Group vs Sex

Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Reaction Group", "Reaction", patient age and sex, and report outcome. A case may describe one or more "Reaction Group", "Reaction", or outcome. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction) in the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". "Reaction" corresponds to the suspected reaction reported by the Reporter. The "Reaction" is based on the MedDRA dictionary Preferred Term (PT). Including one or more of these outcomes or reported reactions in a report does not necessarily mean that the suspect product of interest was the cause of the reported outcomes or reactions. A case may have one or more reported outcomes.

Displayed by Reaction Group and Reaction

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases
621

Serious Cases (including death)
597

Death Cases
67

Received Year	Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Received Date	Ca
<input type="text"/>	13057482	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Blood Gases Abnormal;Bradycardia;Hyp	Serious	Hospitalized;Other Outcomes	Male	-	29-DEC-2017	Ex
<input type="text"/>	14331171	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Hypokalaemia;Overdose... Gases Abnormal;Hypercalcaemia	Serious	Hospitalized;Other Outcomes	Male	-	28-DEC-2017	Ex
<input type="text"/>	13018049	-	Amlodipine Besylate	-	Overdose;Hypotension	Serious	Life Threatening	Male	-	27-DEC-2017	Ex
<input type="text"/>	14324505	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Acute Respiratory Distress Syndrome;Pancreatitis;Hy	Serious	Other Outcomes;Hospitaliz	Female	-	26-DEC-2017	Ex
<input type="text"/>	14300356	Benazepril;Amlodipine	Amlodipine Besylate;Benazepril Hydrochloride	Hypertension	Angioedema;Hypertensi...	Serious	Required Intervention;Hospita	Male	28-NOV-2017	18-DEC-2017	Dis
<input type="text"/>	14290774	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Overdose;Hypotension;... Level Of Consciousness	Serious	Life Threatening;Other Outcomes;Hospitaliz	Female	-	15-DEC-2017	Ex
<input type="text"/>	14278968	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Intentional Overdose;Unresponsive To Stimuli;Hypotension	Serious	Hospitalized;Life Threatening;Other Outcomes	Female	-	13-DEC-2017	Ex
<input type="text"/>	14271675	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Unresponsive To Stimuli;Hypotension;Depr	Serious	Hospitalized;Life Threatening;Other Outcomes	Female	-	11-DEC-2017	Ex

Data as of March 2018
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Total number of cases based on applied filter

Click to Sort

Additional Filter Options

Filter within each displayed column

Scroll to view additional columns

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 621

Serious Cases (including deaths) 597

Death Cases 67

Received Year	Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Received Date	Ca
<input type="text"/>	13057482	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Indication	...	cardia;Hyp	Hospitalized;Other Outcomes	Male	-	29-DEC-2017	Ex
<input type="text"/>	14331171	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Indication	Q	verdose...	Hospitalized;Other Outcomes	Male	-	28-DEC-2017	Ex
<input type="text"/>	13018049	-	Amlodipine Besylate	-	Acne;Gastroesophageal Reflux D... Acute Myeloid Leukemia;Antivira... Adenocarcinoma Of Colon;Hypert...	calcaemia ension	Life Threatening	Male	-	27-DEC-2017	Ex
<input type="text"/>	14324505	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Indication	Angina Pectoris;Antiplatelet Thera... Angina Pectoris;Cardiovascular Di... Angina Pectoris;Coronary Artery... Angina Unstable;Back Pain;Cardio... Antiretroviral Therapy;Product Us...	y ertensi...	Other Outcomes;Hospitaliz	Female	-	26-DEC-2017	Ex
<input type="text"/>	14300356	Benazepril;Amlodipine	Amlodipine Besylate;Benazepril Hydrochloride	Hypertension			Required Intervention;Hospita	Male	28-NOV-2017	18-DEC-2017	Dis
<input type="text"/>	14290774	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Indication		ension;...	Life Threatening;Other Outcomes;Hospitaliz	Female	-	15-DEC-2017	Ex
<input type="text"/>	14278968	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Intentional Overdose;Unresponsive To Stimuli;Hypotension		Hospitalized;Life Threatening;Other Outcomes	Female	-	13-DEC-2017	Ex
<input type="text"/>	14271675	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Unresponsive To Stimuli;Hypotension;Depre Level Of		Hospitalized;Life Threatening;Other Outcomes	Female	-	11-DEC-2017	Ex

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 621

Serious Cases (including deaths) 597

Death Cases 67

Received Year	Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Received Date	Ca
	13057482	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Blood Gases Abnormal;Bradycardia;Hyp	Serious	Hospitalized;Other Outcomes	Male	-	29-DEC-2017	Ex
	14331171	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Hypokalaemia;Overdose... Gases Abnormal;Hypercalcaemia	Serious	Hospitalized;Other Outcomes	Male	-	28-DEC-2017	Ex
	13018049	-	Amlodipine Besylate	-	Overdose;Hypotension	Serious	Life Threatening	Male	-	27-DEC-2017	Ex
	14324505	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Acute Respiratory Distress Syndrome;Pancreatitis;Hyp	Serious	Other Outcomes;Hospitaliz	Female	-	26-DEC-2017	Ex
	14300356	Benazepril;Amlodipine	Amlodipine Besylate;Benazepril Hydrochloride	Hypertension	Angioedema;Hypertens...	Serious	Required Intervention;Hospita	Male	28-NOV-2017	18-DEC-2017	Dis
	14290774	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Overdose;Hypotension;... Level Of Consciousness	Serious	Life Threatening;Other Outcomes;Hospitaliz	Female	-	15-DEC-2017	Ex
	14278968	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Intentional Overdose;Unresponsive To Stimuli;Hypotension	Serious	Hospitalized;Life Threatening;Other Outcomes	Female	-	13-DEC-2017	Ex
	14271675	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Unresponsive To Stimuli;Hypotension;Depr	Serious	Hospitalized;Life Threatening;Other Outcomes	Female	-	11-DEC-2017	Ex

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 621

Serious Cases (including deaths) 597

Death Case 67

Export

Received Year	Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Event Date	Latest FDA Received Date	Ca
<input type="text" value="Case Priority"/>	13057482	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Blood Gases Abnormal;Bradycardia;Hyp	Serious	Hospitalized;Other Outcomes	Male	-	29-DEC-2017	Ex
<input type="text" value="Serious"/>	14331171	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Hypokalaemia;Overdose... Gases Abnormal;Hypercalcaemia	Serious	Hospitalized;Other Outcomes	Male	-	28-DEC-2017	Ex
<input type="text" value="Outcome"/>	13018049	-	Amlodipine Besylate	-	Overdose;Hypotension	Serious	Life Threatening	Male	-	27-DEC-2017	Ex
<input type="text" value="Reason for Use"/>	14324505	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Acute Respiratory Distress Syndrome;Pancreatitis;Hyp	Serious	Other Outcomes;Hospitaliz	Female	-	26-DEC-2017	Ex
<input type="text" value="Age Group"/>	14300356	Benazepril;Amlodipine	Amlodipine Besylate;Benazepril Hydrochloride	Hypertension	Angioedema;Hypertensi...	Serious	Required Intervention;Hospita	Male	28-NOV-2017	18-DEC-2017	Dii
<input type="text" value="Sex"/>	14290774	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Overdose;Hypotension;... Level Of Consciousness	Serious	Life Threatening;Other Outcomes;Hospitaliz	Female	-	15-DEC-2017	Ex
<input type="text" value="Sender"/>	14278968	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Intentional Overdose;Unresponsive To Stimuli;Hypotension	Serious	Hospitalized;Life Threatening;Other Outcomes	Female	-	13-DEC-2017	Ex
<input type="text" value="Reporter Region"/>	14271675	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Unresponsive To Stimuli;Hypotension;Depre	Serious	Hospitalized;Life Threatening;Other Outcomes	Female	-	11-DEC-2017	Ex

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AMLODIPINE BESYLATE (G); AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (P)

Total Cases 621

Serious Cases (including deaths) 597

Case 17

Received Year	Case ID	Suspect Product Names	Suspect Product Active Ingredients	Reason for Use	Reactions	Serious	Outcomes	Sex	Case	Date	Export
	13057482	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Blood Gases Abnormal;Bradycardia;Hyp...	Serious	Hospitalized;Other Outcomes	Male			
	14331171	Amlodipine;Benazepril	Benazepril Hydrochloride;Amlodipine Besylate	Product Used For Unknown Indication	Hypokalaemia;Overdose... Gases Abnormal;Hypercalcaemia	Serious	Hospitalized;Other Outcomes	Male		28-DEC-2017	Ex
	13018049	-	Amlodipine Besylate	-	Overdose;Hypotension	Serious	Life Threatening	Male		27-DEC-2017	Ex
	14324505	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Acute Respiratory Distress Syndrome;Pancreatitis;Hy...	Serious	Other Outcomes;Hospitaliz	Female		26-DEC-2017	Ex
	14300356	Benazepril;Amlodipine	Amlodipine Besylate;Benazepril Hydrochloride	Hypertension	Angioedema;Hypertensi...	Serious	Required Intervention;Hospita	Male		28-NOV-2017	Dis
	14290774	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Overdose;Hypotension;... Level Of Consciousness	Serious	Life Threatening;Other Outcomes;Hospitaliz	Female		15-DEC-2017	Ex
	14278968	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Intentional Overdose;Unresponsive To Stimuli;Hypotension	Serious	Hospitalized;Life Threatening;Other Outcomes	Female		13-DEC-2017	Ex
	14271675	Amlodipine	Amlodipine Besylate;Carvedilol	Product Used For Unknown Indication	Unresponsive To Stimuli;Hypotension;Depre...	Serious	Hospitalized;Life Threatening;Other Outcomes	Female		11-DEC-2017	Ex

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SEARCH BY REACTION TERMS



No selections applied

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Search by Product Search by Reaction Term *(Up to 5 reaction terms can be selected)*

Go

Click to search by reaction term. This field provides a smart search capability

SEARCH BY REACTION TERMS



No selections applied

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Search by Product Search by Reaction Term (Up to 5 reaction terms can be selected)

fati x

Chronic Fatigue Syndrome	R
Mental Fatigue	R
Muscle Fatigue	R
Needle Fatigue	R
Post Viral Fatigue Syndrome	R
Respiratory Fatigue	R

Selected Reaction Terms (4 of 5 allowed reaction terms selected)

Dizziness	R
Drug Hypersensitivity	R
Hypotension	R
Fatigue	R

Select "Respiratory Fatigue"

R – Reaction Terms

Selected Reactions (up to 5 allowed)

Go

Click on "Go" to run the search

DEMOGRAPHICS



Reaction Term 4 of 18768
Received Year 6 of 51
Country Domestic
Age Group 3 of 8

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DIZZINESS; DRUG HYPERSENSITIVITY; FATIGUE; HYPOTENSION

Total Cases
225,706

Serious Cases (including deaths)
89,412

Death Cases
6,949

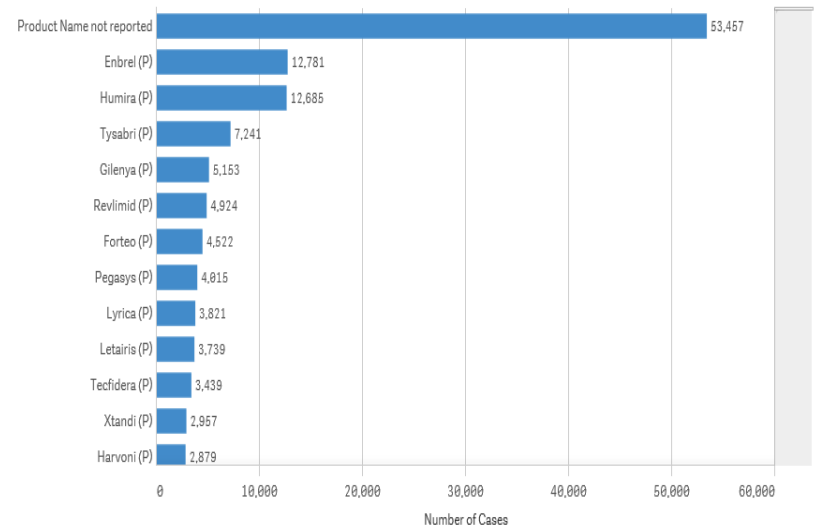


Cases by Product Name

Case Count by Product Name

Category	Number of Cases	Percentage
Product Name not reported	53,457	23.68%
Enbrel (P)	12,781	5.66%
Humira (P)	12,685	5.62%
Tysabri (P)	7,241	3.21%
Gilenya (P)	5,153	2.28%
Revlimid (P)	4,924	2.18%
Forteo (P)	4,522	2.00%
Pegasys (P)	4,015	1.78%
Lyrica (P)	3,821	1.69%
Letairis (P)	3,739	1.66%
Tecfidera (P)	3,439	1.52%
Xtandi (P)	2,957	1.31%
Harvoni (P)	2,879	1.28%
Totals	225,706	100.00%

Case Count by Product Name



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Product Name". "Product Name" is the reported trade or brand name of the product. "Reported as Generic" indicates cases for which only generic name of the product was reported and trade or brand name was not reported.

DEMOGRAPHICS



Cases by Generic Name

Reaction Term: 4 of 18768
Received Year: 6 of 51
Country: Domestic
Age Group: 3 of 8

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DIZZINESS; DRUG HYPERSENSITIVITY; FATIGUE; HYPOTENSION



Total Cases
225,706

Serious Cases (including deaths)
89,412

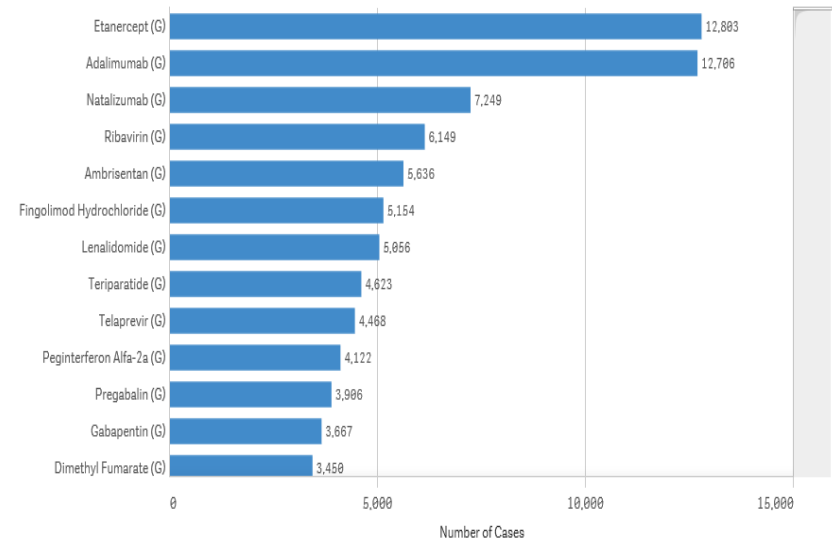
Death Cases
6,949

Cases by Generic Name

Case Count by Generic Name

Category	Q	Number of Cases	Percentage
Etanercept (G)		12,883	5.67%
Adalimumab (G)		12,706	5.63%
Natalizumab (G)		7,249	3.21%
Ribavirin (G)		6,149	2.72%
Ambrisentan (G)		5,636	2.50%
Fingolimod Hydrochloride (G)		5,154	2.28%
Lenalidomide (G)		5,056	2.24%
Teriparatide (G)		4,623	2.05%
Telaprevir (G)		4,468	1.98%
Peginterferon Alfa-2a (G)		4,122	1.83%
Pregabalin (G)		3,906	1.73%
Gabapentin (G)		3,667	1.62%
Dimethyl Fumarate (G)		3,450	1.53%
Totals		225,706	100.00%

Case Count by Generic Name



Data as of March 31, 2018

This page displays the number of cases identified for the product/reaction term of interest by "Generic Name". "Generic Name" is the reported generic name of the product.

CONCLUSION

- ❑ FAERS dashboard gives the consumer, healthcare professionals and industry a more user friendly platform for accessing FAERS reports
- ❑ FAERS dashboard makes adverse event data more accessible and transparent.
- ❑ Existence of a report does not establish causation
- ❑ Rates of occurrence cannot be established with FAERS reports

