

Provision of Publicly Available FAERs Data for Kevzara® (Sarilumab)

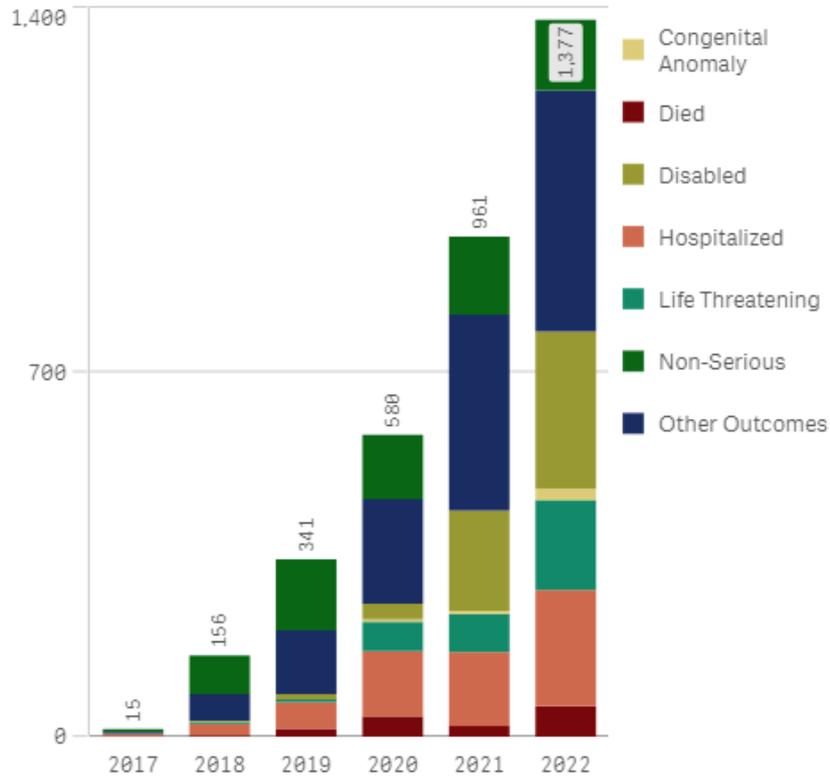
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and streamline post-market drug adverse event data collection and assessment.

The FDA's Adverse Event Reporting System (FDA AERS or FAERs), is a publicly available database which contains more than 28 million deidentified reports of AEs. Information from the FAERs public dashboard has been *pre-filtered to Kevzara® (Sarilumab) and all infections*, with data as of 30 June 2022.

The information provided below is for **information purposes only**, when using this data, you should be aware that there are a number of limitations, these are described in detail in this document and available on the FAERs public dashboard website. If you have any questions related to Kevzara please contact the manufacturer Sanofi-Aventis on 1-800-633-1610.

Pre-filtered to Kevzara® (Sarilumab) and ALL INFECTIONS, with data as of 30 June 2022.

Outcome counts by Received Year



Case counts by Age Group and Sex

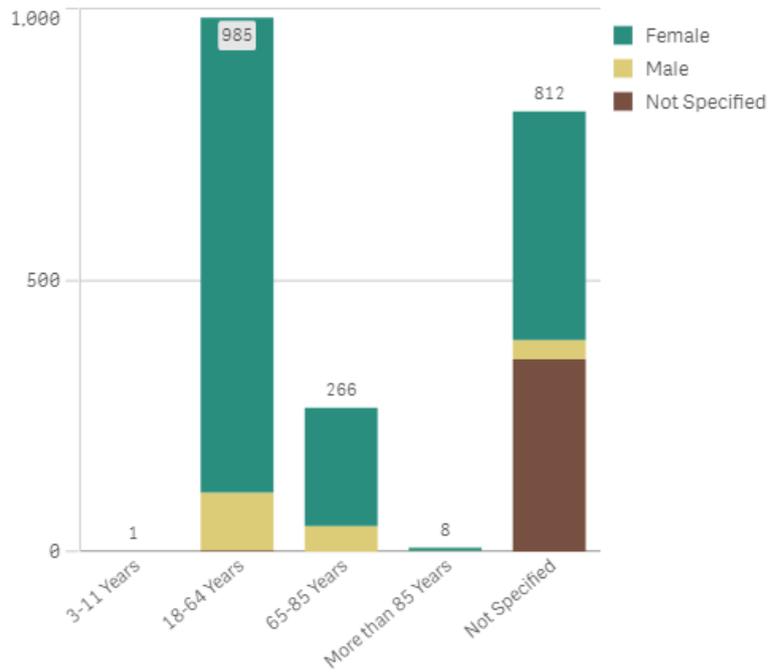


Table of Adverse Events of Infections (*Keyzara*® (*Sarilumab*)) with data as of 30 June 2022

Reaction Term	Count	Reaction Term	Count
Helicobacter Infection	526	Streptococcal Infection	2
Infection	436	Fungal Sepsis	2
Nasopharyngitis	354	Serratia Infection	2
Sinusitis	271	Bursitis Infective	2
Pneumonia	263	Soft Tissue Infection	2
Lower Respiratory Tract Infection	202	Dermatophytosis Of Nail	2
Folliculitis	188	Abscess Oral	2
Covid-19	155	Infection Parasitic	2
Urinary Tract Infection	137	Klebsiella Bacteraemia	2
Ear Infection	98	Carbuncle	2
Herpes Zoster	69	Haemorrhagic Pneumonia	2
Laryngitis	65	Cytomegalovirus Infection	1
Retinitis	64	Mastitis	1
Influenza	62	Clostridium Difficile Infection	1
Upper Respiratory Tract Infection	61	Clostridium Difficile Colitis	1
Bronchitis	59	Labyrinthitis	1
Wound Infection	56	Encephalitis	1
Cellulitis	46	Meningitis	1
Sepsis	34	Helicobacter Gastritis	1
Diverticulitis	34	Pancreas Infection	1
Staphylococcal Infection	31	Cellulitis Staphylococcal	1
Onychomycosis	30	Lyme Disease	1
Septic Shock	28	Chronic Sinusitis	1
Pneumonia Bacterial	26	Epstein-Barr Virus Infection	1
Localised Infection	24	Atypical Pneumonia	1
Fungal Infection	23	Klebsiella Sepsis	1
Lupus Vulgaris	22	Pneumonia Staphylococcal	1
Cystitis	20	Neutropenic Sepsis	1
Viral Infection	20	Endophthalmitis	1
Respiratory Tract Infection	17	Tooth Abscess	1
Pharyngitis Streptococcal	16	Acute Sinusitis	1
Tooth Infection	14	Lower Respiratory Tract Infection Fungal	1
Eye Infection	13	Breast Abscess	1
Bacteraemia	13	Acarodermatitis	1
Kidney Infection	12	Fungal Skin Infection	1
Oral Herpes	11	Root Canal Infection	1
Pharyngitis	10	Hordeolum	1
Candida Infection	10	Renal Abscess	1
Bacterial Infection	9	Pneumonia Klebsiella	1
Skin Infection	9	Purulence	1
Arthritis Infective	9	Pulmonary Tuberculosis	1
Staphylococcal Bacteraemia	9	Escherichia Urinary Tract Infection	1
Peritonitis	8	Rectal Abscess	1
Abscess	8	Pyelonephritis Chronic	1
Infectious Pleural Effusion	8	Meningitis Bacterial	1
Keratitis Bacterial	8	Pustule	1
Upper Respiratory Tract Infection Bacterial	8	Paronychia	1
Subcutaneous Abscess	7	Hepatitis B	1
Injection Site Infection	6	Mycobacterium Avium Complex Infection	1
Gastroenteritis Viral	6	Respiratory Tract Infection Viral	1

Endocarditis Bacterial	6	Herpes Ophthalmic	1
Arthritis Bacterial	6	Abscess Jaw	1
Impetigo	6	Superinfection	1
Oral Infection	6	Intervertebral Discitis	1
Coronavirus Infection	6	Gastric Infection	1
Abscess Limb	5	Infective Exacerbation Of Chronic Obstructive Airways Disease	1
Post Procedural Infection	5	Pseudomonal Bacteraemia	1
Rhinitis	5	Abscess Intestinal	1
Oral Candidiasis	5	Nasal Abscess	1
Pseudomonas Infection	5	Blister Infected	1
Tuberculosis	5	Urinary Tract Infection Bacterial	1
Enterococcal Infection	5	Nail Infection	1
Infected Skin Ulcer	5	Myelitis	1
Suspected Covid-19	5	Prostate Infection	1
Osteomyelitis	4	Tracheobronchitis	1
Gingivitis	4	Infected Bite	1
Abdominal Abscess	4	Bacterial Disease Carrier	1
Pneumonia Pseudomonal	4	Enterobacter Infection	1
Pyelonephritis	4	Histoplasmosis	1
Furuncle	4	Mycoplasma Infection	1
Conjunctivitis	3	Pneumonia Necrotising	1
Escherichia Infection	3	American Trypanosomiasis	1
Fungaemia	3	Medical Device Site Joint Infection	1
Pneumocystis Jirovecii Pneumonia	3	Enterococcal Bacteraemia	1
Herpes Virus Infection	3	Genital Abscess	1
Necrotising Fasciitis	3	Croup Infectious	1
Purulent Discharge	3	Eczema Infected	1
Gastrointestinal Infection	3	Gastrointestinal Bacterial Overgrowth	1
Pneumonia Aspiration	3	Large Intestine Infection	1
Anal Abscess	3	Enterobacter Pneumonia	1
Rash Pustular	3	Septic Necrosis	1
Abdominal Infection	3	Tinea Versicolour	1
Device Related Sepsis	3	Graft Infection	1
Systemic Candida	3	Coccidioidomycosis	1
Groin Abscess	3	Perineal Abscess	1
Postoperative Wound Infection	3	Wound Infection Bacterial	1
Covid-19 Pneumonia	3	Joint Tuberculosis	1
Deltia Acidovorans Infection	3	Bartholin'S Abscess	1
Herpetic Radiculopathy	3	Genitourinary Tract Infection	1
Device Related Infection	2	Fungal Foot Infection	1
Appendicitis Perforated	2	Viral Diarrhoea	1
Hepatitis C	2	Enterobacter Bacteraemia	1
Appendicitis	2	Oesophageal Infection	1
Gangrene	2	Dermatitis Infected	1
Staphylococcal Sepsis	2	Herpes Simplex Reactivation	1
Bronchopulmonary Aspergillosis	2	Infective Tenosynovitis	1
Endocarditis	2	Cystitis Klebsiella	1
Urosepsis	2	Wound Sepsis	1
Bacterial Sepsis	2	Necrotising Soft Tissue Infection	1
Injection Site Cellulitis	2	Systemic Infection	1
Streptococcal Bacteraemia	2	Atypical Mycobacterial Pneumonia	1
Herpes Simplex	2	Purulent Synovitis	1
Infection Susceptibility Increased	2	Medical Device Site Cellulitis	1

Pneumonia Streptococcal	2	Systemic Bacterial Infection	1
Pyelonephritis Acute	2	Bifidobacterium Infection	1
Bone Abscess	2	Asymptomatic Covid-19	1
Cytomegalovirus Colitis	2	Diverticulitis Intestinal Perforated	1
Periodontitis	2		
Klebsiella Infection	2		
Bronchiolitis	2		

Limitations of FAERs Data

- **The information retrieved from the FAERS database should not be used to draw any conclusions** regarding the safety of the medicinal products as individual reports do not imply causality of the product. The output is not considered “CDS” and are not intended to be designed, implemented, provided and/or used to influence clinical decisions or as clinical decision support (CDS).
- **FAERs is significantly limited by underreporting:** Despite the significant increases in AE reporting, limitations in the use of FAERS data for post-market surveillance remain. One of the biggest limitations is that not all adverse events are reported. As a spontaneous (i.e., voluntary) reporting system, it’s simply not possible for every adverse event to be recorded. A systematic review of underreporting estimates that is 94%⁴. Therefore, the number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of the adverse event in association with the drug.
- **Rates of occurrence cannot be established with reports:** 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 and are significantly impacted by the Weber effect which is often summarised by stating that AE reporting peaks at the end of the second year after.
- **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.
- **Information in reports has not been verified:** Safety reports submitted to FDA does not mean that the information included in it has been medically confirmed and does not reflect a conclusion by FDA or the marketing authorisation holder that the information in the report constitutes an admission that the drug caused or contributed to an adverse event.