

Supplement – list of all signals in children

Event	Reports	PRR (95% CI)	SOC
Salbutamol, inhaled (ATC code: R03AC02)			
Therapeutic and nontherapeutic responses	149	4.5 (3.9-5.3)	General disorders and administration site conditions
Bronchospasm and obstruction	143	11.5 (9.9-13.5)	Respiratory, thoracic and mediastinal disorders
Rate and rhythm disorders NEC	135	7.6 (6.5-8.9)	Cardiac disorders
Breathing abnormalities	123	3.2 (2.7-3.8)	Respiratory, thoracic and mediastinal disorders
Product quality issues NEC	85	21.3 (17.3-26.2)	Product issues
Product administration errors and issues	80	2.3 (1.8-2.8)	Injury, poisoning and procedural complications
Tremor (excl congenital)	67	6.7 (5.3-8.5)	Nervous system disorders
Supraventricular arrhythmias	43	16.4 (12.1-22.0)	Cardiac disorders
Anxiety symptoms	41	2.4 (1.8-3.2)	Psychiatric disorders
Overdoses NEC	39	2.2 (1.6-3.0)	Injury, poisoning and procedural complications
Coughing and associated symptoms	39	2.1 (1.6-2.9)	Respiratory, thoracic and mediastinal disorders
Potassium imbalance	38	17.4 (12.6-23.9)	Metabolism and nutrition disorders
Metabolic acidoses (excl diabetic acidoses)	38	11.7 (8.5-16.1)	Metabolism and nutrition disorders
Cardiac signs and symptoms NEC	36	2.8 (2.0-3.9)	Cardiac disorders
Medication errors, product use errors and issues NEC	32	2.5 (1.8-3.6)	Injury, poisoning and procedural complications
Lower respiratory tract and lung infections	28	2.2 (1.5-3.2)	Infections and infestations
Blood gas and acid base analyses	28	6.6 (4.5-9.5)	Investigations
Heart rate and pulse investigations	27	5.2 (3.6-7.6)	Investigations
Bullous conditions	26	1.7 (1.1-2.4)	Skin and subcutaneous tissue disorders
Off label uses	22	2.4 (1.6-3.7)	Injury, poisoning and procedural complications
Ventricular arrhythmias and cardiac arrest	20	2.8 (1.8-4.4)	Cardiac disorders
Respiratory tract disorders NEC	18	4.3 (2.7-6.8)	Respiratory, thoracic and mediastinal disorders
Hyperglycaemic conditions NEC	17	6.6 (4.1-10.6)	Metabolism and nutrition disorders
Behaviour and socialisation disturbances	17	1.8 (1.1-2.9)	Psychiatric disorders
Accidental exposures to product	17	2.4 (1.5-3.9)	Injury, poisoning and procedural complications

Conditions associated with abnormal gas exchange	16	5.5 (3.3-8.9)	Respiratory, thoracic and mediastinal disorders
ECG investigations	15	5.3 (3.2-8.8)	Investigations
Thermal burns	13	35.4 (20.1-62.2)	Injury, poisoning and procedural complications
Respiratory failures (excl neonatal)	13	3.4 (2.0-5.8)	Respiratory, thoracic and mediastinal disorders
Poisoning and toxicity	13	1.8 (1.1-3.1)	Injury, poisoning and procedural complications
Interactions	13	3.1 (1.8-5.3)	General disorders and administration site conditions
Intentional product misuses	13	10.2 (5.9-17.7)	Injury, poisoning and procedural complications
Pupil disorders	12	3.3 (1.9-5.8)	Eye disorders
Non-site specific vascular disorders NEC	9	3.9 (2.0-7.5)	Vascular disorders
Psychotic disorder NEC	8	3.3 (1.6-6.6)	Psychiatric disorders
Lower respiratory tract signs and symptoms	8	4.1 (2.0-8.1)	Infections and infestations
Device issues NEC	8	7.0 (3.5-14.0)	Product issues
Carbohydrate tolerance analyses (incl diabetes)	8	2.6 (1.3-5.1)	Investigations
Respiratory and pulmonary function diagnostic procedures	6	15.3 (6.8-34.5)	Investigations
Device malfunction events NEC	6	13.1 (5.8-29.6)	Product issues
Respiratory signs and symptoms NEC	5	9.5 (3.9-23.1)	Respiratory, thoracic and mediastinal disorders
Musculoskeletal and connective tissue disorders of limbs congenital	5	2.5 (1.0-6.0)	Musculoskeletal and connective tissue disorders
Terbutaline (ATC code: R03AC03)			
Rate and rhythm disorders NEC	16	11.5 (7.5-17.8)	Cardiac disorders
Tremor (excl congenital)	9	11.6 (6.3-21.4)	Nervous system disorders
Overdoses NEC	5	3.7 (1.6-8.6)	Injury, poisoning and procedural complications
Gestational age and weight conditions	5	9.2 (3.9-21.5)	Pregnancy, puerperium and perinatal conditions
Cardiac signs and symptoms NEC	5	5.0 (2.2-11.8)	Cardiac disorders
Salmeterol (ATC code: R03AC12)			
Rate and rhythm disorders NEC	6	9.8 (4.8-20.3)	Cardiac disorders
Formoterol (ATC code: R03AC13)			
Bronchospasm and obstruction	18	16.8 (11.2-25.3)	Respiratory, thoracic and mediastinal disorders
Rate and rhythm disorders NEC	9	5.9 (3.2-10.9)	Cardiac disorders
Overdoses NEC	7	4.7 (2.3-9.6)	Injury, poisoning and procedural complications
Exposures associated with pregnancy,	6	4.0 (1.8-8.6)	Injury, poisoning and procedural

delivery and lactation			complications
Coughing and associated symptoms	5	3.2 (1.4-7.5)	Respiratory, thoracic and mediastinal disorders
Salmeterol + fluticasone (ATC code: R03AK06)			
Bronchospasm and obstruction	154	20.9 (18.2-24.0)	Respiratory, thoracic and mediastinal disorders
Therapeutic and nontherapeutic responses	61	3.1 (2.4-3.9)	General disorders and administration site conditions
Product quality issues NEC	54	22.3 (17.2-28.8)	Product issues
Coughing and associated symptoms	54	4.9 (3.8-6.4)	Respiratory, thoracic and mediastinal disorders
Breathing abnormalities	42	1.8 (1.4-2.4)	Respiratory, thoracic and mediastinal disorders
Product administration errors and issues	40	1.9 (1.4-2.6)	Injury, poisoning and procedural complications
Upper respiratory tract signs and symptoms	36	4.6 (3.4-6.3)	Respiratory, thoracic and mediastinal disorders
Overdoses NEC	30	2.9 (2.0-4.1)	Injury, poisoning and procedural complications
Headaches NEC	30	1.5 (1.1-2.1)	Nervous system disorders
Adrenal cortical hypofunctions	30	57.4 (39.9-82.6)	Metabolism and nutrition disorders
Lower respiratory tract and lung infections	26	3.4 (2.4-5.0)	Infections and infestations
Rate and rhythm disorders NEC	23	2.1 (1.4-3.2)	Cardiac disorders
Off label uses	23	4.3 (2.8-6.4)	Injury, poisoning and procedural complications
Behaviour and socialisation disturbances	23	4.1 (2.7-6.1)	Psychiatric disorders
Musculoskeletal and connective tissue signs and symptoms NEC	21	4.7 (3.1-7.1)	Musculoskeletal and connective tissue disorders
Upper respiratory tract infections	19	1.9 (1.2-2.9)	Infections and infestations
Anxiety symptoms	18	1.8 (1.1-2.8)	Psychiatric disorders
Abnormal behaviour NEC	18	3.1 (2.0-4.9)	Psychiatric disorders
Cardiac signs and symptoms NEC	16	2.1 (1.3-3.4)	Cardiac disorders
Parasomnias	13	7.8 (4.6-13.5)	Psychiatric disorders
Adrenal cortex tests	13	71.9 (40.8-126.7)	Investigations
Oral soft tissue swelling and oedema	12	3.7 (2.1-6.5)	Gastrointestinal disorders
Adrenal cortical hyperfunctions	11	19.2 (10.6-34.8)	Metabolism and nutrition disorders
Visual disorders NEC	10	2.2 (1.2-4.2)	Eye disorders
Ventricular arrhythmias and cardiac arrest	9	2.1 (1.1-4.1)	Cardiac disorders
Increased intracranial pressure disorders	9	4.3 (2.2-8.2)	Nervous system disorders

Glaucomas (excl congenital)	9	34.0 (17.5-66.2)	Eye disorders
Therapeutic procedures NEC	8	3.6 (1.8-7.1)	General disorders and administration site conditions
Sleep disorders NEC	7	2.8 (1.4-5.9)	Psychiatric disorders
Interactions	7	2.8 (1.3-5.8)	General disorders and administration site conditions
Hypoglycaemic conditions NEC	7	2.9 (1.4-6.0)	Metabolism and nutrition disorders
Confusion and disorientation	7	2.2 (1.0-4.5)	Psychiatric disorders
Cataract conditions	7	23.6 (11.2-50.0)	Eye disorders
Tic disorders	6	5.7 (2.6-12.7)	Psychiatric disorders
Oral soft tissue disorders NEC	6	7.0 (3.1-15.5)	Gastrointestinal disorders
Ischaemic coronary artery disorders	6	12.1 (5.4-27.0)	Cardiac disorders
Supraventricular arrhythmias	5	3.1 (1.3-7.4)	Cardiac disorders
Skin hypoplasias and atrophies	5	20.3 (8.4-49.3)	Skin and subcutaneous tissue disorders
Optic disc abnormalities NEC	5	7.4 (3.1-17.7)	Eye disorders
Memory loss (excl dementia)	5	3.1 (1.3-7.4)	Nervous system disorders
Candida infections	5	6.1 (2.5-14.6)	Infections and infestations
Formoterol + budesonide (ATC code: R03AK07)			
Bronchospasm and obstruction	43	20.1 (15.5-25.9)	Respiratory, thoracic and mediastinal disorders
Therapeutic and nontherapeutic responses	18	3.2 (2.1-4.9)	General disorders and administration site conditions
Product administration errors and issues	16	2.7 (1.7-4.3)	Injury, poisoning and procedural complications
Medication errors, product use errors and issues NEC	14	6.5 (4.0-10.8)	Injury, poisoning and procedural complications
Breathing abnormalities	14	2.1 (1.3-3.5)	Respiratory, thoracic and mediastinal disorders
Coughing and associated symptoms	12	3.8 (2.2-6.6)	Respiratory, thoracic and mediastinal disorders
Off label uses	11	7.1 (4.0-12.6)	Injury, poisoning and procedural complications
Headaches NEC	11	1.9 (1.1-3.4)	Nervous system disorders
Upper respiratory tract signs and symptoms	9	4.0 (2.1-7.6)	Respiratory, thoracic and mediastinal disorders
Physical examination procedures and organ system status	9	2.8 (1.5-5.2)	Investigations
Tremor (excl congenital)	6	3.5 (1.6-7.7)	Nervous system disorders
Suicidal and self-injurious behaviour	6	2.6 (1.2-5.7)	Psychiatric disorders
Lower respiratory tract and lung infections	6	2.8 (1.3-6.1)	Infections and infestations
Intentional product misuses	5	22.8 (9.6-54.3)	Injury, poisoning and procedural complications
Allergies to foods, food additives,	5	9.7 (4.1-22.9)	Immune system disorders

drugs and other chemicals

Ipratropium bromide (ATC code: R03BA01)

Bronchospasm and obstruction	20	8.8 (5.9-13.4)	Respiratory, thoracic and mediastinal disorders
Urticarias	15	2.6 (1.6-4.3)	Immune system disorders
Coughing and associated symptoms	13	4.0 (2.3-6.7)	Respiratory, thoracic and mediastinal disorders
Anxiety symptoms	10	3.3 (1.8-6.0)	Psychiatric disorders
Erythemas	9	2.2 (1.1-4.1)	Skin and subcutaneous tissue disorders
Pruritus NEC	8	2.2 (1.1-4.3)	Skin and subcutaneous tissue disorders
Musculoskeletal and connective tissue signs and symptoms NEC	8	5.9 (3.0-11.7)	Musculoskeletal and connective tissue disorders
Upper respiratory tract signs and symptoms	7	3.0 (1.4-6.2)	Respiratory, thoracic and mediastinal disorders
Suicidal and self-injurious behaviour	7	2.9 (1.4-5.9)	Psychiatric disorders
Sleep disorders NEC	6	8.1 (3.7-17.8)	Psychiatric disorders
Behaviour and socialisation disturbances	6	3.5 (1.6-7.7)	Psychiatric disorders
Off label uses	5	3.1 (1.3-7.3)	Injury, poisoning and procedural complications
Candida infections	5	20.4 (8.6-48.6)	Infections and infestations
Abnormal behaviour NEC	5	2.9 (1.2-6.8)	Psychiatric disorders

Budesonide (ATC code: R03BA02)

Bronchospasm and obstruction	103	13.4 (11.2-16.0)	Respiratory, thoracic and mediastinal disorders
Breathing abnormalities	56	2.4 (1.8-3.0)	Respiratory, thoracic and mediastinal disorders
Coughing and associated symptoms	44	3.9 (2.9-5.2)	Respiratory, thoracic and mediastinal disorders
Therapeutic and nontherapeutic responses	43	2.1 (1.6-2.8)	General disorders and administration site conditions
Upper respiratory tract signs and symptoms	28	3.5 (2.4-5.0)	Respiratory, thoracic and mediastinal disorders
Medication errors, product use errors and issues NEC	28	3.6 (2.5-5.2)	Injury, poisoning and procedural complications
Lower respiratory tract and lung infections	24	3.1 (2.1-4.5)	Infections and infestations
Upper respiratory tract infections	22	2.1 (1.4-3.2)	Infections and infestations
Adrenal cortical hypofunctions	22	39.8 (26.1-60.7)	Metabolism and nutrition disorders
Off label uses	21	3.8 (2.5-5.7)	Injury, poisoning and procedural complications
Behaviour and socialisation disturbances	21	3.6 (2.4-5.5)	Psychiatric disorders

Anxiety symptoms	21	2.0 (1.3-3.0)	Psychiatric disorders
Allergic conditions NEC	18	2.0 (1.3-3.2)	Immune system disorders
Musculoskeletal and connective tissue signs and symptoms NEC	17	3.7 (2.3-5.8)	Musculoskeletal and connective tissue disorders
Cataract conditions	17	58.5 (35.8-95.5)	Eye disorders
Emotional and mood disturbances NEC	16	1.6 (1.0-2.6)	Psychiatric disorders
Cardiac signs and symptoms NEC	16	2.0 (1.2-3.3)	Cardiac disorders
Adrenal cortical hyperfunctions	14	23.8 (14.1-40.4)	Metabolism and nutrition disorders
Interactions	12	4.6 (2.7-8.2)	General disorders and administration site conditions
Viral infections NEC	11	2.3 (1.3-4.1)	Infections and infestations
White blood cell analyses	10	3.0 (1.6-5.6)	Investigations
Gestational age and weight conditions	10	2.3 (1.2-4.3)	Pregnancy, puerperium and perinatal conditions
Psychotic disorder NEC	9	6.0 (3.1-11.6)	Psychiatric disorders
Immune and associated conditions NEC	9	3.5 (1.9-6.8)	Immune system disorders
Heart rate and pulse investigations	9	2.8 (1.5-5.3)	Investigations
Conditions associated with abnormal gas exchange	9	4.9 (2.6-9.5)	Respiratory, thoracic and mediastinal disorders
Leukopenias NEC	8	3.5 (1.7-6.9)	Immune system disorders
Candida infections	8	9.5 (4.7-19.0)	Infections and infestations
Adrenal cortex tests	8	41.1 (20.2-83.6)	Investigations
Respiratory tract disorders NEC	7	2.7 (1.3-5.6)	Respiratory, thoracic and mediastinal disorders
Intentional product misuses	7	8.8 (4.2-18.5)	Injury, poisoning and procedural complications
Stomatitis and ulceration	6	3.0 (1.4-6.7)	Gastrointestinal disorders
Cardiac septal defects congenital	6	3.8 (1.7-8.5)	Cardiac disorders
Pseudomonal infections	5	14.7 (6.1-35.5)	Infections and infestations
Pituitary analyses anterior	5	8.4 (3.5-20.1)	Investigations
Metabolic bone disorders	5	12.7 (5.3-30.6)	Musculoskeletal and connective tissue disorders
Hypertrichoses	5	17.8 (7.3-43.1)	Skin and subcutaneous tissue disorders

Fluticasone (ATC code: R03BA05)

Bronchospasm and obstruction	68	13.1 (10.5-16.3)	Respiratory, thoracic and mediastinal disorders
Therapeutic and nontherapeutic responses	34	2.5 (1.8-3.4)	General disorders and administration site conditions
Behaviour and socialisation disturbances	32	8.2 (5.9-11.4)	Psychiatric disorders
Lower respiratory tract and lung infections	30	5.7 (4.1-8.1)	Infections and infestations

Coughing and associated symptoms	30	3.9 (2.8-5.6)	Respiratory, thoracic and mediastinal disorders
Product administration errors and issues	26	1.8 (1.2-2.6)	Injury, poisoning and procedural complications
Product quality issues NEC	25	14.6 (10.0-21.5)	Product issues
Adrenal cortical hypofunctions	22	59.5 (39.1-90.4)	Metabolism and nutrition disorders
Upper respiratory tract infections	20	2.8 (1.9-4.4)	Infections and infestations
Anxiety symptoms	20	2.8 (1.8-4.3)	Psychiatric disorders
Abnormal behaviour NEC	19	4.7 (3.0-7.3)	Psychiatric disorders
Overdoses NEC	18	2.5 (1.6-3.9)	Injury, poisoning and procedural complications
Off label uses	18	4.8 (3.1-7.6)	Injury, poisoning and procedural complications
Musculoskeletal and connective tissue signs and symptoms NEC	18	5.8 (3.7-9.1)	Musculoskeletal and connective tissue disorders
Emotional and mood disturbances NEC	17	2.6 (1.6-4.1)	Psychiatric disorders
Upper respiratory tract signs and symptoms	16	3.0 (1.8-4.8)	Respiratory, thoracic and mediastinal disorders
Physical examination procedures and organ system status	14	1.8 (1.1-3.0)	Investigations
Dyskinesias and movement disorders NEC	13	2.3 (1.3-3.9)	Nervous system disorders
Allergic conditions NEC	11	1.8 (1.0-3.3)	Immune system disorders
Increased physical activity levels	8	2.4 (1.2-4.8)	Psychiatric disorders
Nasal disorders NEC	7	5.0 (2.4-10.5)	Respiratory, thoracic and mediastinal disorders
Disturbances in initiating and maintaining sleep	7	2.4 (1.1-5.0)	Psychiatric disorders
Cataract conditions	7	34.1 (16.2-72.1)	Eye disorders
Adrenal cortical hyperfunctions	7	17.5 (8.3-36.7)	Metabolism and nutrition disorders
Ocular disorders NEC	6	2.3 (1.0-5.1)	Eye disorders
Bone disorders NEC	6	10.3 (4.6-22.9)	Musculoskeletal and connective tissue disorders
Adrenal cortex tests	6	45.3 (20.1-102.1)	Investigations
Mental impairment (excl dementia and memory loss)	5	2.8 (1.2-6.6)	Psychiatric disorders
Hypoglycaemic conditions NEC	5	2.9 (1.2-7.1)	Metabolism and nutrition disorders
General nutritional disorders NEC	5	2.9 (1.2-6.9)	Metabolism and nutrition disorders
Dental and periodontal infections and inflammations	5	46.2 (18.9-112.7)	Gastrointestinal disorders
Mometasone (ATC code: R03BA07)			

Breathing abnormalities	8	6.3 (3.5-11.5)	Respiratory, thoracic and mediastinal disorders
Rashes, eruptions and exanthems NEC	6	2.6 (1.3-5.4)	Skin and subcutaneous tissue disorders
Product administration errors and issues	5	4.3 (1.9-9.7)	Injury, poisoning and procedural complications
Ciclesonide (ATC code: R03BA08)			
Bronchospasm and obstruction	10	20.7 (12.2-35.1)	Respiratory, thoracic and mediastinal disorders
Breathing abnormalities	5	3.4 (1.5-7.7)	Respiratory, thoracic and mediastinal disorders
Ipratropium bromide (ATC code: R03BB01)			
Rate and rhythm disorders NEC	15	9.3 (5.9-14.7)	Cardiac disorders
Urticarias	8	2.8 (1.4-5.4)	Immune system disorders
Pupil disorders	8	24.3 (12.6-47.1)	Eye disorders
Product administration errors and issues	8	2.5 (1.3-4.9)	Injury, poisoning and procedural complications
Erythemas	7	3.3 (1.6-6.8)	Skin and subcutaneous tissue disorders
Anaphylactic and anaphylactoid responses	7	4.6 (2.3-9.4)	Immune system disorders
Tremor (excl congenital)	6	6.6 (3.1-14.3)	Nervous system disorders
Coughing and associated symptoms	6	3.6 (1.7-7.8)	Respiratory, thoracic and mediastinal disorders
Cromoglicic acid (ATC code: R03BC01)			
Bronchospasm and obstruction	7	15.4 (7.9-29.7)	Respiratory, thoracic and mediastinal disorders
Breathing abnormalities	6	4.3 (2.1-8.9)	Respiratory, thoracic and mediastinal disorders
Salbutamol, systemic (ATC code: R03CC02)			
Rate and rhythm disorders NEC	102	8.0 (6.7-9.6)	Cardiac disorders
Bronchospasm and obstruction	94	10.5 (8.7-12.7)	Respiratory, thoracic and mediastinal disorders
Breathing abnormalities	75	2.7 (2.2-3.4)	Respiratory, thoracic and mediastinal disorders
Therapeutic and nontherapeutic responses	69	2.9 (2.3-3.7)	General disorders and administration site conditions
Tremor (excl congenital)	49	6.9 (5.2-9.0)	Nervous system disorders
Product administration errors and issues	46	1.8 (1.4-2.4)	Injury, poisoning and procedural complications
Supraventricular arrhythmias	38	20.2 (14.7-27.6)	Cardiac disorders
Metabolic acidoses (excl diabetic acidoses)	37	16.0 (11.6-22.0)	Metabolism and nutrition disorders
Urticarias	35	1.5 (1.1-2.1)	Immune system disorders
Potassium imbalance	35	22.3 (16.1-31.1)	Metabolism and nutrition disorders

Anxiety symptoms	33	2.7 (1.9-3.8)	Psychiatric disorders
Overdoses NEC	31	2.5 (1.8-3.5)	Injury, poisoning and procedural complications
Coughing and associated symptoms	30	2.3 (1.6-3.2)	Respiratory, thoracic and mediastinal disorders
Cardiac signs and symptoms NEC	30	3.3 (2.3-4.7)	Cardiac disorders
Product quality issues NEC	28	9.5 (6.6-13.7)	Product issues
Bullous conditions	24	2.2 (1.5-3.2)	Skin and subcutaneous tissue disorders
Heart rate and pulse investigations	23	6.2 (4.1-9.3)	Investigations
Medication errors, product use errors and issues NEC	22	2.4 (1.6-3.7)	Injury, poisoning and procedural complications
Lower respiratory tract and lung infections	19	2.1 (1.3-3.3)	Infections and infestations
Blood gas and acid base analyses	18	5.9 (3.7-9.3)	Investigations
Respiratory tract disorders NEC	15	5.0 (3.0-8.2)	Respiratory, thoracic and mediastinal disorders
Off label uses	15	2.3 (1.4-3.8)	Injury, poisoning and procedural complications
ECG investigations	15	7.4 (4.5-12.3)	Investigations
Hyperglycaemic conditions NEC	14	7.6 (4.5-12.8)	Metabolism and nutrition disorders
Ventricular arrhythmias and cardiac arrest	13	2.6 (1.5-4.4)	Cardiac disorders
Vascular hypotensive disorders	13	2.1 (1.2-3.6)	Vascular disorders
Poisoning and toxicity	13	2.5 (1.5-4.3)	Injury, poisoning and procedural complications
Conditions associated with abnormal gas exchange	13	6.2 (3.6-10.6)	Respiratory, thoracic and mediastinal disorders
Behaviour and socialisation disturbances	13	1.9 (1.1-3.3)	Psychiatric disorders
Respiratory failures (excl neonatal)	11	4.0 (2.2-7.2)	Respiratory, thoracic and mediastinal disorders
Perception disturbances	11	1.8 (1.0-3.3)	Psychiatric disorders
Pupil disorders	10	3.8 (2.1-7.1)	Eye disorders
Interactions	9	3.0 (1.6-5.8)	General disorders and administration site conditions
Psychotic disorder NEC	8	4.6 (2.3-9.2)	Psychiatric disorders
Device issues NEC	7	8.5 (4.1-17.9)	Product issues
Non-site specific vascular disorders NEC	6	3.6 (1.6-8.1)	Vascular disorders
Lower respiratory tract signs and symptoms	6	4.3 (1.9-9.5)	Infections and infestations
Intentional product misuses	6	6.5 (2.9-14.5)	Injury, poisoning and procedural complications
Carbohydrate tolerance analyses (incl	6	2.7 (1.2-6.0)	Investigations

diabetes)			
Thermal burns	5	18.1 (7.4-43.9)	Injury, poisoning and procedural complications
Respiratory signs and symptoms NEC	5	13.3 (5.5-32.3)	Respiratory, thoracic and mediastinal disorders
Terbutaline, systemic (ATC code: R03CC03)			
Rate and rhythm disorders NEC	22	13.3 (9.3-19.1)	Cardiac disorders
Tremor (excl congenital)	11	11.9 (6.8-20.7)	Nervous system disorders
Overdoses NEC	9	5.6 (3.0-10.4)	Injury, poisoning and procedural complications
Potassium imbalance	6	28.8 (13.3-62.6)	Metabolism and nutrition disorders
Gestational age and weight conditions	6	9.3 (4.3-20.1)	Pregnancy, puerperium and perinatal conditions
Theophylline (ATC code: R03DA04)			
Seizures and seizure disorders NEC	27	4.3 (3.1-6.0)	Nervous system disorders
Nausea and vomiting symptoms	20	2.8 (1.9-4.1)	Gastrointestinal disorders
Rate and rhythm disorders NEC	12	6.4 (3.8-10.9)	Cardiac disorders
Breathing abnormalities	12	3.0 (1.8-5.1)	Respiratory, thoracic and mediastinal disorders
Poisoning and toxicity	10	13.4 (7.5-24.2)	Injury, poisoning and procedural complications
Bronchospasm and obstruction	9	6.8 (3.7-12.8)	Respiratory, thoracic and mediastinal disorders
Therapeutic drug monitoring analyses	8	17.4 (8.9-33.8)	Investigations
Overdoses NEC	8	4.4 (2.3-8.6)	Injury, poisoning and procedural complications
Potassium imbalance	7	29.9 (14.6-61.3)	Metabolism and nutrition disorders
Interactions	6	13.8 (6.4-30.1)	General disorders and administration site conditions
Exposures associated with pregnancy, delivery and lactation	6	3.3 (1.5-7.1)	Injury, poisoning and procedural complications
Encephalopathies NEC	6	9.8 (4.5-21.4)	Nervous system disorders
Dyskinesias and movement disorders NEC	5	3.5 (1.5-8.3)	Nervous system disorders
Abnormal behaviour NEC	5	4.9 (2.1-11.6)	Psychiatric disorders
Zafirlukast (ATC code: R03DC01)			
Interactions	5	38.9 (17.5-86.5)	General disorders and administration site conditions
Bronchospasm and obstruction	5	12.9 (5.8-28.5)	Respiratory, thoracic and mediastinal disorders
Montelukast (ATC code: R03DC03)			
Overdoses NEC	350	8.9 (8.1-9.9)	Injury, poisoning and procedural complications
Behaviour and socialisation	328	16.0 (14.4-17.8)	Psychiatric disorders

disturbances			
Parasomnias	252	49.5 (43.3-56.6)	Psychiatric disorders
Anxiety symptoms	249	6.4 (5.7-7.2)	Psychiatric disorders
Emotional and mood disturbances NEC	247	6.9 (6.1-7.7)	Psychiatric disorders
Suicidal and self-injurious behaviour	219	7.1 (6.3-8.1)	Psychiatric disorders
Abnormal behaviour NEC	211	9.7 (8.5-11.1)	Psychiatric disorders
Disturbances in initiating and maintaining sleep	163	10.4 (8.9-12.1)	Psychiatric disorders
Perception disturbances	153	8.0 (6.9-9.4)	Psychiatric disorders
Depressive disorders	142	10.2 (8.6-12.0)	Psychiatric disorders
Headaches NEC	123	1.6 (1.3-1.9)	Nervous system disorders
Product administration errors and issues	118	1.4 (1.2-1.7)	Injury, poisoning and procedural complications
Adverse effect absent	118	4.1 (3.4-4.9)	General disorders and administration site conditions
Gastrointestinal and abdominal pains (excl oral and throat)	116	2.1 (1.8-2.5)	Gastrointestinal disorders
Dyskinesias and movement disorders NEC	100	3.2 (2.6-3.8)	Nervous system disorders
Bronchospasm and obstruction	95	3.2 (2.7-4.0)	Respiratory, thoracic and mediastinal disorders
Fear symptoms and phobic disorders (incl social phobia)	72	27.5 (21.5-35.1)	Psychiatric disorders
Mood alterations with depressive symptoms	67	8.0 (6.3-10.2)	Psychiatric disorders
Sleep disorders NEC	66	7.0 (5.5-9.0)	Psychiatric disorders
Increased physical activity levels	63	3.4 (2.7-4.3)	Psychiatric disorders
Speech articulation and rhythm disturbances	61	6.3 (4.9-8.1)	Psychiatric disorders
Feelings and sensations NEC	61	1.8 (1.4-2.2)	General disorders and administration site conditions
Fluctuating mood symptoms	59	20.6 (15.8-26.9)	Psychiatric disorders
Coughing and associated symptoms	56	1.3 (1.0-1.7)	Respiratory, thoracic and mediastinal disorders
Musculoskeletal and connective tissue pain and discomfort	48	1.4 (1.1-1.9)	Musculoskeletal and connective tissue disorders
Tremor (excl congenital)	45	1.9 (1.4-2.6)	Nervous system disorders
Mental impairment (excl dementia and memory loss)	45	4.5 (3.3-6.0)	Psychiatric disorders
Paraesthesias and dysaesthesias	43	2.0 (1.5-2.7)	Nervous system disorders
Nasal disorders NEC	43	5.6 (4.1-7.5)	Respiratory, thoracic and mediastinal disorders
Upper respiratory tract signs and symptoms	42	1.4 (1.0-1.9)	Respiratory, thoracic and mediastinal disorders
Attention deficit and disruptive	33	14.8 (10.4-21.0)	Psychiatric disorders

behaviour disorders			
Tic disorders	32	8.1 (5.7-11.5)	Psychiatric disorders
Obsessive-compulsive disorders and symptoms	32	14.8 (10.4-21.3)	Psychiatric disorders
Mood disorders NEC	32	2.5 (1.7-3.5)	Psychiatric disorders
Product quality issues NEC	31	3.2 (2.3-4.6)	Product issues
Panic attacks and disorders	30	10.7 (7.4-15.5)	Psychiatric disorders
Muscle related signs and symptoms NEC	29	1.7 (1.2-2.4)	Musculoskeletal and connective tissue disorders
Thinking disturbances	28	15.4 (10.5-22.7)	Psychiatric disorders
Confusion and disorientation	25	2.0 (1.3-2.9)	Psychiatric disorders
Mental disorders NEC	23	5.8 (3.8-8.7)	Psychiatric disorders
Sleep disturbances NEC	22	4.6 (3.0-7.0)	Psychiatric disorders
Affect alterations NEC	21	9.3 (6.0-14.4)	General disorders and administration site conditions
Personality disorders NEC	20	23.3 (14.6-37.1)	Psychiatric disorders
Psychotic disorder NEC	18	3.2 (2.0-5.1)	Psychiatric disorders
Educational issues	18	26.0 (15.8-42.6)	Social circumstances
Psychiatric elimination disorders	17	12.7 (7.8-20.8)	Psychiatric disorders
Skin injuries NEC	15	2.2 (1.3-3.7)	Skin and subcutaneous tissue disorders
Gastrointestinal disorders NEC	15	2.9 (1.8-4.9)	Gastrointestinal disorders
Product confusion errors and issues	14	37.2 (20.9-66.3)	Injury, poisoning and procedural complications
Memory loss (excl dementia)	14	2.2 (1.3-3.8)	Nervous system disorders
Vasculitides	13	90.7 (46.3-177.9)	Vascular disorders
Sensory abnormalities NEC	13	2.2 (1.3-3.8)	Nervous system disorders
Criminal activity	12	12.4 (6.9-22.3)	Psychiatric disorders
Oral dryness and saliva altered	11	1.8 (1.0-3.3)	Gastrointestinal disorders
Eyelid movement disorders	10	3.9 (2.1-7.2)	Eye disorders
Dyspeptic signs and symptoms	10	4.7 (2.5-8.7)	Gastrointestinal disorders
Anxiety disorders NEC	10	14.8 (7.8-28.3)	Psychiatric disorders
Stereotypies and automatisms	9	4.4 (2.3-8.5)	Psychiatric disorders
Absence seizures	9	2.5 (1.3-4.9)	Nervous system disorders
Vasculitides NEC	7	2.6 (1.2-5.5)	Vascular disorders
Impulse control disorders	7	6.1 (2.9-12.9)	Psychiatric disorders
Lacrimation disorders	6	2.4 (1.1-5.3)	Eye disorders
Product dispensing errors and issues	5	2.9 (1.2-6.9)	Injury, poisoning and procedural complications
Panniculitides	5	4.8 (2.0-11.8)	Skin and subcutaneous tissue disorders
Neurological disorders congenital NEC	5	3.7 (1.5-9.0)	Nervous system disorders
Dental and periodontal infections and	5	8.1 (3.3-19.9)	Gastrointestinal disorders

inflammations			
Bleeding tendencies	5	6.1 (2.5-14.8)	Blood and lymphatic system disorders
Omalizumab (ATC code: R03DX05)			
Bronchospasm and obstruction	212	23.8 (21.2-26.8)	Respiratory, thoracic and mediastinal disorders
Breathing abnormalities	92	3.3 (2.7-4.0)	Respiratory, thoracic and mediastinal disorders
Anaphylactic and anaphylactoid responses	86	7.0 (5.8-8.6)	Immune system disorders
Urticarias	64	2.7 (2.2-3.5)	Immune system disorders
Asthenic conditions	61	2.2 (1.7-2.7)	Psychiatric disorders
Headaches NEC	59	2.4 (1.9-3.1)	Nervous system disorders
Pruritus NEC	56	3.8 (2.9-4.9)	Skin and subcutaneous tissue disorders
Coughing and associated symptoms	56	4.2 (3.3-5.4)	Respiratory, thoracic and mediastinal disorders
Allergic conditions NEC	55	5.3 (4.1-6.8)	Immune system disorders
Pain and discomfort NEC	54	3.2 (2.5-4.2)	General disorders and administration site conditions
Upper respiratory tract signs and symptoms	45	4.7 (3.6-6.3)	Respiratory, thoracic and mediastinal disorders
Neurological signs and symptoms NEC	38	1.6 (1.2-2.2)	Nervous system disorders
Upper respiratory tract infections	32	2.6 (1.8-3.6)	Infections and infestations
Erythemas	32	1.9 (1.3-2.6)	Skin and subcutaneous tissue disorders
Exposures associated with pregnancy, delivery and lactation	29	2.2 (1.6-3.2)	Injury, poisoning and procedural complications
Feelings and sensations NEC	27	2.5 (1.7-3.6)	General disorders and administration site conditions
Angioedemas	25	2.8 (1.9-4.1)	Immune system disorders
Peripheral vascular disorders NEC	24	5.7 (3.8-8.5)	Vascular disorders
Musculoskeletal and connective tissue pain and discomfort	24	2.2 (1.5-3.3)	Musculoskeletal and connective tissue disorders
Lower respiratory tract and lung infections	24	2.6 (1.8-3.9)	Infections and infestations
Physical examination procedures and organ system status	22	1.6 (1.0-2.4)	Investigations
Immunoglobulin analyses	20	43.8 (27.9-68.6)	Investigations
Joint related signs and symptoms	18	2.5 (1.6-4.0)	Musculoskeletal and connective tissue disorders
Dermatitis and eczema	18	3.3 (2.1-5.2)	Skin and subcutaneous tissue disorders
Paraesthesias and dysaesthesias	16	2.4 (1.5-3.9)	Nervous system disorders
Oral soft tissue swelling and oedema	16	4.0 (2.5-6.6)	Gastrointestinal disorders

Gestational age and weight conditions	15	2.9 (1.8-4.8)	Pregnancy, puerperium and perinatal conditions
Vascular tests NEC (incl blood pressure)	14	3.4 (2.0-5.7)	Investigations
Ocular disorders NEC	14	3.0 (1.8-5.1)	Eye disorders
Vascular hypotensive disorders	12	1.9 (1.1-3.3)	Vascular disorders
Heart rate and pulse investigations	12	3.1 (1.8-5.5)	Investigations
Gastrointestinal signs and symptoms NEC	12	3.3 (1.9-5.8)	Gastrointestinal disorders
Visual disorders NEC	11	2.0 (1.1-3.6)	Eye disorders
Nasal congestion and inflammations	11	8.6 (4.8-15.6)	Respiratory, thoracic and mediastinal disorders
Tongue signs and symptoms	10	5.8 (3.1-10.8)	Gastrointestinal disorders
Speech and language abnormalities	9	2.2 (1.1-4.1)	Nervous system disorders
Respiratory and pulmonary function diagnostic procedures	9	32.1 (16.5-62.6)	Investigations
Non-site specific injuries NEC	9	1.9 (1.0-3.7)	Injury, poisoning and procedural complications
Ocular infections, inflammations and associated manifestations	8	4.2 (2.1-8.3)	Eye disorders
Migraine headaches	8	5.6 (2.8-11.2)	Nervous system disorders
Respiratory tract disorders NEC	7	2.3 (1.1-4.7)	Respiratory, thoracic and mediastinal disorders
Pharyngeal disorders (excl infections and neoplasms)	7	2.6 (1.2-5.5)	Gastrointestinal disorders
Influenza viral infections	7	3.6 (1.7-7.6)	Infections and infestations
Limb fractures and dislocations	6	7.9 (3.6-17.7)	Injury, poisoning and procedural complications
Exfoliative conditions	6	3.1 (1.4-7.0)	Skin and subcutaneous tissue disorders
Allergies to foods, food additives, drugs and other chemicals	6	2.7 (1.2-6.0)	Immune system disorders
Sensory abnormalities NEC	5	2.7 (1.1-6.5)	Nervous system disorders
Red blood cell analyses	5	2.8 (1.2-6.8)	Investigations
Oral soft tissue pain and paraesthesia	5	6.7 (2.8-16.3)	Gastrointestinal disorders
Fractures and dislocations NEC	5	12.1 (5.0-29.2)	Injury, poisoning and procedural complications