Table S1. Overview of the available information on adverse infant events in the FAERS database and in LactMed® for the 25 selected products.

N: Nervous system	FAERS	LactMed®
Buprenorphine	Bradycardia Coma scale abnormal Drug withdrawal syndrome Neonatal Hypoglycemia Hypotension Irritability Lethargy Miosis Poor feeding infant Selective eating disorder Somnolence Sudden death	Agitation Drowsiness Drug withdrawal Frequent yawning Hyperactive Moro reflex Insomnia Lower milk intake Lower weight gain Myoclonic jerks Opioid abstinence Poor feeding Pupillary dilation Sneezing Sweating Tremors
Lamotrigine	Abdominal pain Abnormal loss of weight Apathy Bradyarrhythmia Cyanosis neonatal Ecchymosis Eczema Failure to thrive Fatigue Feeding disorder Fluid intake reduced Hepatic enzyme increased Hyperbilirubinemia neonatal Hypotonia neonatal Hypovolemic shock Infantile apnea Irritability Jaundice Laryngomalacia Lethargy Liver disorder Malnutrition Nausea Neonatal hypoxia Neutropenia Normochromic normocytic Anemia Poor feeding infant Poor weight gain neonatal Rash Rash maculo-papular	Anemia Apneic episode Drowsiness Drug withdrawal Elevated liver enzymes Elevated platelet counts Feeding problems Gangrene Gastrointestinal symptoms Heart murmur Hypotonia Icterus prolongatus Irritability Jaundice Liver damage Loss of appetite Neuromotor hyperexcitability Persistent crying Rash Retractive breathing Sedation Transient neutropenia Weight loss

	Rhinorrhea Selective eating disorder Skin discoloration Sleep disorder Somnolence Stridor Supraventricular Extrasystoles Thrombocytosis Urticaria Vomiting	
Levetiracetam	Anemia neonatal Heart rate increased Infantile apnea Cyanosis neonatal Blood bilirubin increased Failure to thrive	Drowsiness Hypotonia Poor feeding infant Poor weight gain Sedation Vomiting Weight loss Withdrawal seizures
Acetaminophen	Abdominal distension Acute hepatic failure Asthma Blood pressure abnormal Capillary nail refill test abnormal Coagulopathy Crying Drug-induced liver injury Erythema Gastrointestinal hemorrhage Hemoglobin decreased Heart rate increased Hepatomegaly Hypoglycemia Irritability Jaundice Livedo reticularis Metabolic acidosis Poor feeding infant Pulse abnormal Pyrexia Respiratory distress Respiratory syncytial virus bronchiolitis Selective eating disorder Shock Skin exfoliation Staphylococcal infection	Asthma Maculopapular rash on the upper trunk and face Wheezing

	Upper gastrointestinal hemorrhage Vomiting Wheezing	
Nicotine	Dyspnea	Reduction in the heart rate Sudden infant death syndrome
L: Antineoplastic and immunomodulating agents		
Certolizumab pegol	Agitation Fungal infection Hematochezia Hematoma Irritability Nervousness Rash Restlessness Selective eating disorder Tongue disorder Wound	Candida infection Upper respiratory infection Vomiting
Adalimumab	Nasopharyngitis Irritability Intestinal hemorrhage Gastrointestinal disorder	None reported
Etanercept	Blood bilirubin abnormal Blood glucose decreased Death Dermatitis atopic Diarrhea Disturbance in attention Dyslexia Enterocolitis Feeding intolerance Gastroesophageal reflux Disease Gross motor delay Hemoglobin decreased Jaundice neonatal Lung disorder Nasopharyngitis Pneumonia Rash macular Respiratory tract congestion Seborrheic dermatitis Selective eating disorder Viral infection	High-pitched crying Rash

	Weight decreased Weight gain poor White blood cell count increased	
Infliximab	Hematochezia Jaundice Lactose intolerance Lower respiratory tract infection Lymph gland infection Malaise Poor feeding infant Selective eating disorder	None reported
Tacrolimus	Diarrhea Intraventricular hemorrhage neonatal Neonatal asphyxia Neonatal respiratory distress syndrome Pneumothorax	None reported
A: Alimentary tract and metabolism		
Insulin	Gastroesophageal reflux disease Hematochezia Necrotizing colitis	None reported
Omeprazole	Diarrhea Faeces discolored Zinc deficiency	None reported
Ondansetron hydrochloride	Crying Insomnia Irritability Sluggishness	None reported
Mesalamine	Abdominal pain upper Blood albumin abnormal Candida infection Colitis Diarrhea Hematochezia Hemoglobin abnormal Pyrexia White blood cell count increased	Diarrhea Thrombocytosis Thrombosis
Metformin hydrochloride	Tremor	None reported

J: Antiinfectives for systemic use		
Zanamivir	Abnormal faeces Decreased appetite	No information
Amoxicillin/Clavulanic acid	Agitation Clostridium difficile colitis Conversion disorder Diarrhea Enterocolitis Eye swelling Gastrointestinal pain Hematochezia Oral candidiasis Pyrexia Rash maculo-papular Rectal hemorrhage Vomiting	Constipation Diarrhea Elevated liver enzymes (AST and ALT) Generalized urticaria Rash Restlessness
Tenofovir disoproxil fumarate	Thrombocytopenia	Diarrhea
Lamivudine	Sudden infant death syndrome	Sudden infant death syndrome
Emtricitabine/Tenofovir	-	Diarrhea
R: Respiratory system		
Omalizumab	Anemia Anaphylactic reaction Cough Decreased appetite Eczema Eye oedema Gastroesophageal reflux disease Nasopharyngitis Oral fungal infection Otitis externa Poor quality sleep Pyrexia Rash erythematous Seborrheic dermatitis Swelling face	None reported
Fluticasone propionate/Salmeterol xinafoate	Middle insomnia Poor feeding infant	None reported
Cetirizine hydrochloride	Abnormal faeces Cyanosis	Bruising Colicky symptoms

	Floppy infant Lethargy Oxygen saturation decreased Rash Respiratory arrest Somnolence	Constipation Drowsiness Fever Irritability Poor feeding Rash Refusing of the breast Sedation
Elexacaftor\Ivacaftor\Tezacaftor	Alanine aminotransferase increased Aspartate aminotransferase increased Bronchiolitis Hyperinsulinemia Hypoglycemia neonatal Jaundice neonatal Neonatal respiratory distress Pancreatic failure Sepsis neonatal Sweat test abnormal Transient tachypnoea of the newborn Viral infection	Bilirubin abnormalities Liver enzyme abnormalities Low sweat chloride
Budesonide	Adrenocortical insufficiency neonatal Dermatitis Eczema Neutropenia	None reported