This serves as the response to your Freedom of Information Act (FOIA) request for records regarding adverse event reports received for Solensia (frunevetmab).

A search of CVM's Adverse Drug Event (ADE) database was performed on 4/1/2024.

The search parameters were:

Active ingredient(s): frunevetmab Reports received: From 1-13-2022 through 3-31-2024 Case type: Spontaneous ADE report Species: All Route of administration: All

For each drug (active ingredient), we have provided the '**CVM ADE Comprehensive Clinical Detail Report Listing**', which is a cumulative listing of adverse experiences in reports submitted to CVM.

General Information about CVM's ADE Database

The primary purpose for maintaining the CVM ADE database is to provide an early warning or signaling system to CVM for adverse effects not detected during pre-market testing of FDA-approved animal drugs and for monitoring the performance of drugs not approved for use in animals. Information from these ADE reports is received and coded in an electronic FDA/CVM ADE database. CVM scientists use the ADE database to make decisions about product safety which may include changes to the label or other regulatory action. CVM's ADE reporting system depends on detection and voluntary reporting of adverse clinical events by veterinarians and animal owners.

The Center's ADE review process is complex, and for each report takes into consideration confounding factors such as:

Dosage Concomitant drug use The medical and physical condition of animals at the time of treatment Environmental and management information Product defects Extra-label (off label) uses The specifics of these complex factors cannot be addressed in the CVM ADE Comprehensive Clinical Detail Report Listing.

How to Use the CVM ADE Comprehensive Clinical Detail Report Listing

Clinical signs reported for an active ingredient are listed in order from most frequently reported to least frequently reported, grouped by species and route of administration.

More than one clinical sign may have been reported per ADE case report, so the Number of times reported column is not additive and does not necessarily represent the total number of reports received. Also, if a manufacturer reports multiple products in a single ADE case report, clinical signs are associated with each of the manufacturer's products.

Solensia (frunevetmab) is approved for parenteral use in **cats** only. For the time period of the ADE database search (1-13-2022 to 3-31-2024), there were a total of 3264 ADE reports received for Solensia injectable.

The following shows the number of reports broken down by all species for which reports have been received during this time period:

DRUG: SOLENSIA Number of reports in cats: 3233 Number of reports in dogs: 1 Number of reports in other species: 2 Number of reports in humans, accidental exposure: 28 Total number of Adverse Drug Events in all species: 3264

When reviewing the CVM ADE Comprehensive Clinical Detail Report Listing, the reader should be aware that:

For any given ADE report, there is no certainty that the reported drug caused the adverse event. The adverse event may have been related to an underlying disease, using other drugs at the same time, or other non-drug related causes. The clinical detail listing does not include information about underlying diseases, other drugs used at the same time, other non-drug related causes, or the final outcome of the reaction.

The accuracy of information regarding the ADE is dependent on the quality of information received from the reporting veterinarian or animal owner.

Accumulated ADE reports should not be used to calculate incidence rates or estimates of drug risk, because there is no accurate way to determine how many animals were actually

Name: Solensia inquiries DATE:4/1/2024

given the drug, which is needed as the denominator in calculations of incidence and relative risk.

It is inappropriate to make use of adverse event data to compare the safety of different products. For example, if a drug is widely used to treat certain conditions, there may be more ADEs for that drug than another product that is not used as often. This would not mean that the first drug was more unsafe than the second. The number of reports simply represents the number of ADEs received for a particular drug and should not be used for any type of comparison purposes.

Underreporting occurs with most adverse event reporting systems. The frequency of reporting for a given drug product varies over time, and may be greater when the drug is newly marketed, or when media publicity occurs.

Information on how the drugs were used (for indications on the product label or in an extra label manner) is not provided in the clinical detail listing.

More information about CVM's ADE Reporting System can be found on our web site at: <u>FDA</u>, <u>Animal and Veterinary</u>, <u>Safety and Health page</u>

CVM ADE Comprehensive Clinical Detail Report Listing

Cumulative Date Range : 13-Jan-2022 -thru- 31-Mar-2024 Included 1932a cases = : True Included Medicated Feed cases = : True

DRUG: FRUNEVETMAB

Species: Cat Route of Administration: i Sign: FACIAL PARALYSIS, Number of times reported: 1 Sign: HIND LIMB ATAXIA, Number of times reported: 1 Sign: IMPAIRED PROPRIOCEPTION, Number of times reported: 1 Sign: THIRD EYELID EXTRUSION, Number of times reported: 1 Species: Cat Route of Administration: M Sign: DIARRHOEA, Number of times reported: 3 Sign: LACK OF EFFICACY - NOS, Number of times reported: 2 Sign: LETHARGY, Number of times reported: 2 Sign: VOMITING, Number of times reported: 2 Sign: APPLICATION SITE REACTION NOS, Number of times reported: 1 Sign: APPLICATION SITE SKIN SCALING, Number of times reported: 1 Sign: DERMATITIS, Number of times reported: 1 Sign: DILATED PUPILS, Number of times reported: 1 Sign: DROOLING, Number of times reported: 1 Sign: EMESIS, Number of times reported: 1 Sign: HEAVY BREATHING, Number of times reported: 1 Sign: PRURITUS, Number of times reported: 1 Sign: SCRATCHING, Number of times reported: 1 Sign: SKIN SCAB, Number of times reported: 1 Sign: STAGGERING, Number of times reported: 1 Species: Cat Route of Administration: o Sign: BEHAVIOURAL DISORDER NOS, Number of times reported: 1 Sign: BLOOD IN VOMIT, Number of times reported: 1 Sign: BLOOD LOSS NOS, Number of times reported: 1 Sign: DEATH, Number of times reported: 1 Sign: DEATH BY EUTHANASIA, Number of times reported: 1 Sign: DECREASED RED BLOOD CELL COUNT, Number of times reported: 1 Sign: HYPOTHERMIA, Number of times reported: 1 Sign: MALAISE, Number of times reported: 1 Sign: NOT EATING, Number of times reported: 1

Sign: RENAL FAILURE, Number of times reported: 1 Sign: UNWELL, Number of times reported: 1 Sign: VOMITING, Number of times reported: 1

Species: Cat Route of Administration: s

Sign: VOMITING, Number of times reported: 383 Sign: SKIN SCAB, Number of times reported: 367 Sign: LACK OF EFFICACY - NOS, Number of times reported: 322 Sign: LETHARGY, Number of times reported: 310 Sign: PRURITUS, Number of times reported: 305 Sign: DIARRHOEA, Number of times reported: 184 Sign: DEATH BY EUTHANASIA, Number of times reported: 161 Sign: WEIGHT LOSS, Number of times reported: 155 Sign: NOT EATING, Number of times reported: 152 Sign: DERMATITIS, Number of times reported: 142 Sign: DECREASED APPETITE, Number of times reported: 128 Sign: ANOREXIA, Number of times reported: 122 Sign: ALOPECIA, Number of times reported: 106 Sign: ITCHING, Number of times reported: 101 Sign: SKIN LESION NOS, Number of times reported: 101 Sign: FACIAL PRURITUS, Number of times reported: 97 Sign: DEATH, Number of times reported: 96 Sign: ALOPECIA LOCAL, Number of times reported: 90 Sign: SCRATCHING, Number of times reported: 87 Sign: ATAXIA, Number of times reported: 86 Sign: VOCALISATION, Number of times reported: 85 Sign: HIDING, Number of times reported: 79 Sign: INJECTION SITE PAIN, Number of times reported: 79 Sign: LOCALISED HAIR LOSS, Number of times reported: 75 Sign: HAIR LOSS NOS, Number of times reported: 59 Sign: SEIZURE NOS, Number of times reported: 58 Sign: ELEVATED BLOOD UREA NITROGEN (BUN), Number of times reported: 57 Sign: SKIN SORE, Number of times reported: 56 Sign: ANAEMIA NOS, Number of times reported: 55 Sign: BEHAVIOURAL DISORDER NOS, Number of times reported: 52 Sign: POLYDIPSIA, Number of times reported: 51 Sign: EXCESSIVE CHEWING, LICKING AND/OR GROOMING, Number of times reported: 50 Sign: INAPPROPRIATE URINATION, Number of times reported: 50 Sign: DEHYDRATION, Number of times reported: 48 Sign: EXCORIATION, Number of times reported: 46 Sign: PARTIAL LACK OF EFFICACY, Number of times reported: 46 Sign: NOT HIMSELF/HERSELF, Number of times reported: 45 Sign: CRUST, Number of times reported: 44

Sign: ELEVATED SYMMETRICAL DIMETHYLARGININE (SDMA), Number of times reported: 42 Sign: ELEVATED CREATININE, Number of times reported: 41 Sign: FEVER, Number of times reported: 41 Sign: LAMENESS, Number of times reported: 40 Sign: HYPERGLYCAEMIA, Number of times reported: 39 Sign: LOCALISED ITCHING, Number of times reported: 39 Sign: NOT DRINKING, Number of times reported: 39 Sign: WOUND, Number of times reported: 39 Sign: EMESIS (MULTIPLE), Number of times reported: 37 Sign: PAIN NOS, Number of times reported: 36 Sign: SKIN ULCER, Number of times reported: 36 Sign: AGGRESSION, Number of times reported: 35 Sign: ERYTHEMA, Number of times reported: 35 Sign: HOT SPOT (PYOTRAUMATIC DERMATITIS), Number of times reported: 35 Sign: POLYURIA, Number of times reported: 35 Sign: ELEVATED ALANINE AMINOTRANSFERASE (ALT), Number of times reported: 34 Sign: EMESIS, Number of times reported: 34 Sign: ABNORMAL CYTOLOGY, Number of times reported: 33 Sign: INAPPETENCE, Number of times reported: 33 Sign: CONSTIPATION, Number of times reported: 32 Sign: URINARY TRACT INFECTION, Number of times reported: 32 Sign: DISORIENTATION, Number of times reported: 31 Sign: HYPERPHOSPHATAEMIA, Number of times reported: 31 Sign: LEUCOCYTOSIS NOS, Number of times reported: 31 Sign: OTHER ABNORMAL TEST RESULT NOS, Number of times reported: 31 Sign: REDDENING OF THE SKIN, Number of times reported: 31 Sign: ELEVATED RENAL PARAMETERS, Number of times reported: 29 Sign: MOIST DERMATITIS, Number of times reported: 29 Sign: ABNORMAL RADIOGRAPH FINDING, Number of times reported: 28 Sign: LIMB WEAKNESS, Number of times reported: 28 Sign: LICKING, Number of times reported: 26 Sign: WALKING DIFFICULTY, Number of times reported: 26 Sign: HYPOKALAEMIA, Number of times reported: 25 Sign: WEAKNESS, Number of times reported: 25 Sign: DROOLING, Number of times reported: 24 Sign: PANCREATITIS, Number of times reported: 24 Sign: BACTERIAL SKIN INFECTION NOS, Number of times reported: 23 Sign: IMMEDIATE PAIN UPON INJECTION, Number of times reported: 23 Sign: RENAL FAILURE, Number of times reported: 23 Sign: ANAPHYLAXIS, Number of times reported: 22 Sign: DILATED PUPILS, Number of times reported: 22 Sign: INJECTION SITE ALOPECIA, Number of times reported: 22 Sign: ABNORMAL ULTRASOUND FINDING, Number of times reported: 21

Sign: ELEVATED GLOBULINS, Number of times reported: 21 Sign: HIND LIMB PARESIS, Number of times reported: 21 Sign: INJECTION SITE SCAB, Number of times reported: 21 Sign: HEART MURMUR, Number of times reported: 20 Sign: LATERAL RECUMBENCY, Number of times reported: 20 Sign: NEUTROPHILIA, Number of times reported: 20 Sign: ABRASION, Number of times reported: 19 Sign: AZOTAEMIA, Number of times reported: 19 Sign: INJECTION SITE HAIR LOSS, Number of times reported: 19 Sign: LIMPING, Number of times reported: 19 Sign: RELUCTANT TO MOVE, Number of times reported: 19 Sign: TWITCHING, Number of times reported: 19 Sign: BLINDNESS, Number of times reported: 18 Sign: FALLING, Number of times reported: 18 Sign: HYPOTHERMIA, Number of times reported: 18 Sign: BLOOD IN URINE, Number of times reported: 17 Sign: INAPPROPRIATE DEFECATION, Number of times reported: 17 Sign: ITCHY SKIN, Number of times reported: 17 Sign: MUSCULOSKELETAL DISORDER NOS, Number of times reported: 17 Sign: EAR INFECTION NOS, Number of times reported: 16 Sign: EAR PRURITUS, Number of times reported: 16 Sign: BREATHING DIFFICULTY, Number of times reported: 15 Sign: ELEVATED TOTAL BILIRUBIN, Number of times reported: 15 Sign: HYPERACTIVITY, Number of times reported: 15 Sign: LOCALISED PAIN NOS, Number of times reported: 15 Sign: PANTING, Number of times reported: 15 Sign: PLEURAL EFFUSION, Number of times reported: 15 Sign: SNEEZING, Number of times reported: 15 Sign: STARING, Number of times reported: 15 Sign: URINARY INCONTINENCE, Number of times reported: 15 Sign: ADIPSIA, Number of times reported: 14 Sign: DIABETES, Number of times reported: 14 Sign: ELEVATED SERUM ALKALINE PHOSPHATASE (SAP), Number of times reported: 14 Sign: GENERAL HAIR LOSS, Number of times reported: 14 Sign: INCREASED APPETITE, Number of times reported: 14 Sign: PYODERMA, Number of times reported: 14 Sign: THROMBOCYTOPENIA, Number of times reported: 14 Sign: UNABLE TO JUMP, Number of times reported: 14 Sign: HAEMATURIA, Number of times reported: 13 Sign: HEAD TILT - NEUROLOGICAL DISORDER, Number of times reported: 13 Sign: HIND LIMB ATAXIA, Number of times reported: 13 Sign: KNUCKLING, Number of times reported: 13 Sign: LYMPHOPENIA, Number of times reported: 13

Sign: WOBBLINESS, Number of times reported: 13 Sign: AGITATION, Number of times reported: 12 Sign: ARRHYTHMIA, Number of times reported: 12 Sign: BLOODY DIARRHOEA, Number of times reported: 12 Sign: DECREASED HAEMATOCRIT, Number of times reported: 12 Sign: GAIT ABNORMALITY, Number of times reported: 12 Sign: GLUCOSURIA, Number of times reported: 12 Sign: HYPERTHYROIDISM, Number of times reported: 12 Sign: LOOSE STOOL, Number of times reported: 12 Sign: MONOCYTOSIS, Number of times reported: 12 Sign: NYSTAGMUS, Number of times reported: 12 Sign: PALE MUCOUS MEMBRANE, Number of times reported: 12 Sign: TACHYCARDIA, Number of times reported: 12 Sign: ANXIETY, Number of times reported: 11 Sign: ELEVATED THYROXINE (T4), Number of times reported: 11 Sign: EOSINOPENIA, Number of times reported: 11 Sign: HYPERTENSION, Number of times reported: 11 Sign: HYPOGLYCAEMIA, Number of times reported: 11 Sign: HYPOTENSION, Number of times reported: 11 Sign: PROTEINURIA, Number of times reported: 11 Sign: SKIN IRRITATION, Number of times reported: 11 Sign: SKIN LUMP, Number of times reported: 11 Sign: SWOLLEN LIMB, Number of times reported: 11 Sign: UNSTEADY GAIT, Number of times reported: 11 Sign: BARBERING, Number of times reported: 10 Sign: CIRCLING - NEUROLOGICAL DISORDER, Number of times reported: 10 Sign: DERMAL PLAQUE, Number of times reported: 10 Sign: DYSPNOEA, Number of times reported: 10 Sign: ELEVATED LIVER ENZYMES, Number of times reported: 10 Sign: GENERAL ILLNESS, Number of times reported: 10 Sign: INJECTION SITE PRURITUS, Number of times reported: 10 Sign: INJECTION SITE SWELLING, Number of times reported: 10 Sign: NAUSEA, Number of times reported: 10 Sign: PLANTIGRADE POSTURE, Number of times reported: 10 Sign: RENAL DISORDER NOS, Number of times reported: 10 Sign: ABNORMAL POSTURE NOS, Number of times reported: 9 Sign: COLLAPSE NOS, Number of times reported: 9 Sign: FRACTURE, Number of times reported: 9 Sign: HEAD TREMOR, Number of times reported: 9 Sign: LOCAL SWELLING (NOT APPLICATION SITE), Number of times reported: 9 Sign: NON-REGENERATIVE ANAEMIA, Number of times reported: 9 Sign: OPEN MOUTH BREATHING, Number of times reported: 9 Sign: OTITIS NOS, Number of times reported: 9

Sign: RESTLESSNESS, Number of times reported: 9 Sign: SELF TRAUMA, Number of times reported: 9 Sign: ULCERATIVE DERMATITIS, Number of times reported: 9 Sign: ABNORMAL PUPIL LIGHT REFLEX, Number of times reported: 8 Sign: BLOOD IN VOMIT, Number of times reported: 8 Sign: BRADYCARDIA, Number of times reported: 8 Sign: DECREASED URINE CONCENTRATION, Number of times reported: 8 Sign: ELEVATED AMYLASE, Number of times reported: 8 Sign: GENERAL PAIN, Number of times reported: 8 Sign: GROOMING DISORDER, Number of times reported: 8 Sign: HAIR SHEDDING, Number of times reported: 8 Sign: HIGH BLOOD PRESSURE, Number of times reported: 8 Sign: HYPERAESTHESIA, Number of times reported: 8 Sign: HYPERPROTEINAEMIA, Number of times reported: 8 Sign: IMPAIRED VISION, Number of times reported: 8 Sign: INCREASED SKIN SENSITIVITY, Number of times reported: 8 Sign: INJECTION SITE ITCHING, Number of times reported: 8 Sign: INJECTION SITE REDDENING, Number of times reported: 8 Sign: LYMPHOMA, Number of times reported: 8 Sign: MALAISE, Number of times reported: 8 Sign: OCULAR DISCHARGE, Number of times reported: 8 Sign: QUIET, Number of times reported: 8 Sign: RASH, Number of times reported: 8 Sign: SKIN INFLAMMATION NOS, Number of times reported: 8 Sign: TACHYPNOEA, Number of times reported: 8 Sign: TREMOR, Number of times reported: 8 Sign: URINE ABNORMALITIES NOS, Number of times reported: 8 Sign: ACUTE RENAL FAILURE, Number of times reported: 7 Sign: COLLAPSE OF LEG, Number of times reported: 7 Sign: CONGESTIVE HEART FAILURE, Number of times reported: 7 Sign: DECREASED ACTIVITY, Number of times reported: 7 Sign: DECREASED BOWEL MOVEMENTS, Number of times reported: 7 Sign: DIABETES MELLITUS, Number of times reported: 7 Sign: ELEVATED CREATINE-KINASE (CK), Number of times reported: 7 Sign: ENLARGED LYMPH NODE (LOCALISED), Number of times reported: 7 Sign: GENERALISED WEAKNESS, Number of times reported: 7 Sign: HEAD BOBBING, Number of times reported: 7 Sign: HIGH PANCREATIC-SPECIFIC LIPASE, Number of times reported: 7 Sign: HIND LIMB PARALYSIS, Number of times reported: 7 Sign: INJECTION SITE LUMP, Number of times reported: 7 Sign: ITCHY EARS, Number of times reported: 7 Sign: LEUCOPENIA NOS, Number of times reported: 7 Sign: LOCALISED RASH, Number of times reported: 7

Sign: LOW PLATELET COUNT, Number of times reported: 7 Sign: MYDRIASIS, Number of times reported: 7 Sign: NASAL DISCHARGE, Number of times reported: 7 Sign: NOT URINATING, Number of times reported: 7 Sign: OTITIS EXTERNA, Number of times reported: 7 Sign: PACING, Number of times reported: 7 Sign: PARTIAL ANOREXIA, Number of times reported: 7 Sign: SELF MUTILATION, Number of times reported: 7 Sign: SKIN HAEMORRHAGE NOS, Number of times reported: 7 Sign: SLEEPINESS - SYSTEMIC DISORDER, Number of times reported: 7 Sign: STRAINING TO DEFECATE, Number of times reported: 7 Sign: UNCOMFORTABLE, Number of times reported: 7 Sign: ABDOMINAL PAIN, Number of times reported: 6 Sign: ALOPECIA NOS, Number of times reported: 6 Sign: BALANCE IMPAIRED, Number of times reported: 6 Sign: COUGH, Number of times reported: 6 Sign: CYSTITIS, Number of times reported: 6 Sign: DECREASED BODY TEMPERATURE, Number of times reported: 6 Sign: DISTENSION OF ABDOMEN, Number of times reported: 6 Sign: DRINKING A LOT, Number of times reported: 6 Sign: ELEVATED LIPASE, Number of times reported: 6 Sign: GENERALISED ITCHING, Number of times reported: 6 Sign: HYPERCALCAEMIA, Number of times reported: 6 Sign: HYPERSALIVATION, Number of times reported: 6 Sign: INJECTION SITE DERMATITIS, Number of times reported: 6 Sign: INJECTION SITE LESION, Number of times reported: 6 Sign: INJECTION SITE SARCOMA, Number of times reported: 6 Sign: INTESTINAL DISORDER NOS, Number of times reported: 6 Sign: JOINT SWELLING, Number of times reported: 6 Sign: LIMB NON-WEIGHT BEARING, Number of times reported: 6 Sign: MILIARY DERMATITIS, Number of times reported: 6 Sign: NEOPLASIA NOS, Number of times reported: 6 Sign: NEUTROPENIA, Number of times reported: 6 Sign: PARALYSIS, Number of times reported: 6 Sign: PROPRIOCEPTION DEFICIT, Number of times reported: 6 Sign: PURULENT LESION(S), Number of times reported: 6 Sign: SHAKING, Number of times reported: 6 Sign: SKIN REACTION NOS, Number of times reported: 6 Sign: SUDDEN DEATH, Number of times reported: 6 Sign: UNABLE TO STAND, Number of times reported: 6 Sign: ABDOMINAL DISCOMFORT, Number of times reported: 5 Sign: ANAL AND RECTAL DISORDER NOS, Number of times reported: 5 Sign: ANISOCORIA, Number of times reported: 5

Sign: ARTHRITIS, Number of times reported: 5 Sign: ASCITES, Number of times reported: 5 Sign: BITING - PRURITUS, Number of times reported: 5 Sign: CARDIAC ENLARGEMENT, Number of times reported: 5 Sign: CHEWING - PRURITUS, Number of times reported: 5 Sign: CHRONIC RENAL FAILURE, Number of times reported: 5 Sign: CONFUSION, Number of times reported: 5 Sign: CORNEAL ULCER, Number of times reported: 5 Sign: DECREASED DRINKING, Number of times reported: 5 Sign: DECREASED PACKED CELL VOLUME (PCV), Number of times reported: 5 Sign: DULL, Number of times reported: 5 Sign: ELEVATED ASPARTATE AMINOTRANSFERASE (AST), Number of times reported: 5 Sign: ELEVATED TEMPERATURE, Number of times reported: 5 Sign: EOSINOPHILIA, Number of times reported: 5 Sign: FACIAL SWELLING, Number of times reported: 5 Sign: FEBRILE, Number of times reported: 5 Sign: GAGGING, Number of times reported: 5 Sign: HYPERKALAEMIA, Number of times reported: 5 Sign: HYPOCALCAEMIA, Number of times reported: 5 Sign: HYPONATREMIA, Number of times reported: 5 Sign: HYPOPROTEINAEMIA, Number of times reported: 5 Sign: INCREASED RESPIRATORY RATE, Number of times reported: 5 Sign: INJECTION SITE ULCER, Number of times reported: 5 Sign: ISOSTHENURIA, Number of times reported: 5 Sign: JAUNDICE, Number of times reported: 5 Sign: LICKING AT INJECTION SITE, Number of times reported: 5 Sign: LUMBAR PAIN, Number of times reported: 5 Sign: MENTAL IMPAIRMENT NOS, Number of times reported: 5 Sign: NASAL CONGESTION, Number of times reported: 5 Sign: PANCREAS DISORDER, Number of times reported: 5 Sign: RENAL INSUFFICIENCY, Number of times reported: 5 Sign: RESPIRATORY DISTRESS, Number of times reported: 5 Sign: RESPIRATORY TRACT INFECTION NOS, Number of times reported: 5 Sign: RETCHING, Number of times reported: 5 Sign: STIFF GAIT, Number of times reported: 5 Sign: STIFFNESS NOS, Number of times reported: 5 Sign: THROMBOSIS, Number of times reported: 5 Sign: UNABLE TO RISE, Number of times reported: 5 Sign: VOMITING BILE, Number of times reported: 5 Sign: WEIGHT GAIN, Number of times reported: 5 Sign: ABNORMAL BREATHING, Number of times reported: 4 Sign: ABNORMAL HISTOLOGY NOS, Number of times reported: 4 Sign: ABNORMAL MENACE REFLEX TEST, Number of times reported: 4

Sign: ABNORMAL MOVEMENT NOS, Number of times reported: 4 Sign: ACNE, Number of times reported: 4 Sign: ALLERGIC DERMATITIS, Number of times reported: 4 Sign: BITING -AGGRESSION, Number of times reported: 4 Sign: CERVICAL VENTROFLEXION, Number of times reported: 4 Sign: COGNITIVE DISORDER NOS, Number of times reported: 4 Sign: CRYING, Number of times reported: 4 Sign: DEAFNESS, Number of times reported: 4 Sign: DISCOMFORT NOS, Number of times reported: 4 Sign: DISORIENTED STATE, Number of times reported: 4 Sign: DRY SKIN, Number of times reported: 4 Sign: ELECTROLYTE DISORDER, Number of times reported: 4 Sign: EROSION, Number of times reported: 4 Sign: FLATULENCE, Number of times reported: 4 Sign: FOOTPAD DISORDER NOS, Number of times reported: 4 Sign: FREQUENT URINATION, Number of times reported: 4 Sign: GRAND MAL SEIZURE, Number of times reported: 4 Sign: HEAD PRESSING, Number of times reported: 4 Sign: HEAD SHAKE - BEHAVIOURAL DISORDER, Number of times reported: 4 Sign: HIGH IONIZED CALCIUM (CA; HYPERCALCEMIA, IONIZED), Number of times reported: 4 Sign: HYPERNATREMIA, Number of times reported: 4 Sign: HYPOCHLORAEMIA, Number of times reported: 4 Sign: IMMUNE MEDIATED HAEMOLYTIC ANAEMIA, Number of times reported: 4 Sign: INAPPROPRIATE ELIMINATION NOS, Number of times reported: 4 Sign: INJECTION SITE CRUST, Number of times reported: 4 Sign: INJECTION SITE MASS NOS, Number of times reported: 4 Sign: INJECTION SITE REACTION NOS, Number of times reported: 4 Sign: LESS SOCIAL, Number of times reported: 4 Sign: LYING DOWN, Number of times reported: 4 Sign: MASS NOS, Number of times reported: 4 Sign: MUSCLE ATROPHY, Number of times reported: 4 Sign: MUSCLE WEAKNESS NOS, Number of times reported: 4 Sign: MUSCULOSKELETAL PAIN, Number of times reported: 4 Sign: NEUROLOGICAL SYMPTOMS NOS, Number of times reported: 4 Sign: PINNAE DISORDER, Number of times reported: 4 Sign: PULMONARY DISORDER NOS, Number of times reported: 4 Sign: PUSTULES, Number of times reported: 4 Sign: SCALE, Number of times reported: 4 Sign: SKIN AND TISSUE INFECTION NOS, Number of times reported: 4 Sign: SKIN DISORDERS NOS, Number of times reported: 4 Sign: SWELLING NOS, Number of times reported: 4 Sign: SYSTEMIC DISORDER NOS, Number of times reported: 4 Sign: TENSE ABDOMEN, Number of times reported: 4

Sign: THROMBOEMBOLI, Number of times reported: 4 Sign: ULCERATION NOS, Number of times reported: 4 Sign: UNCONSCIOUS, Number of times reported: 4 Sign: UNCONTROLLED DIABETES, Number of times reported: 4 Sign: UNEXPLAINED DEATH, Number of times reported: 4 Sign: UNKEMPT HAIR COAT, Number of times reported: 4 Sign: VESTIBULAR DISORDER NOS, Number of times reported: 4 Sign: WHEEZING, Number of times reported: 4 Sign: APPETITE LOSS, Number of times reported: 3 Sign: ARCHED BACK, Number of times reported: 3 Sign: BALANCE PROBLEM, Number of times reported: 3 Sign: BLOOD CLOT, Number of times reported: 3 Sign: BONE AND JOINT DISORDER NOS, Number of times reported: 3 Sign: CARDIAC ARREST, Number of times reported: 3 Sign: CIRCLING - BEHAVIOURAL DISORDER, Number of times reported: 3 Sign: CLAW / HOOF / NAIL DISORDER NOS, Number of times reported: 3 Sign: COLLAPSE, Number of times reported: 3 Sign: DECREASED RED BLOOD CELL COUNT, Number of times reported: 3 Sign: DERMAL MASS, Number of times reported: 3 Sign: DERMATOSIS NOS, Number of times reported: 3 Sign: DIGESTIVE TRACT DISORDER NOS, Number of times reported: 3 Sign: DISCOLOURED URINE, Number of times reported: 3 Sign: DISTRESS, Number of times reported: 3 Sign: EPIPHORA, Number of times reported: 3 Sign: EPISTAXIS, Number of times reported: 3 Sign: FAECAL INCONTINENCE, Number of times reported: 3 Sign: FLAKING SKIN, Number of times reported: 3 Sign: FOAMING AT THE MOUTH, Number of times reported: 3 Sign: FOUND DEAD, Number of times reported: 3 Sign: GLAZED EYE, Number of times reported: 3 Sign: GROWLING, Number of times reported: 3 Sign: HAIR COAT DISCOLOURATION, Number of times reported: 3 Sign: HARSH LUNG SOUNDS, Number of times reported: 3 Sign: HEAD SHAKE - EAR DISORDER, Number of times reported: 3 Sign: HYPERMETRIA, Number of times reported: 3 Sign: HYPERPIGMENTATION, Number of times reported: 3 Sign: ICTERUS, Number of times reported: 3 Sign: IMPAIRED PROPRIOCEPTION, Number of times reported: 3 Sign: INFLAMMATORY BOWEL DISORDER, Number of times reported: 3 Sign: INJECTION SITE ERYTHEMA, Number of times reported: 3 Sign: INTERVERTEBRAL DISC DISEASE, Number of times reported: 3 Sign: INVOLUNTARY DEFECATION, Number of times reported: 3 Sign: IRRITABILITY, Number of times reported: 3

Sign: LABOURED BREATHING, Number of times reported: 3 Sign: LISTLESS, Number of times reported: 3 Sign: LIVER DISORDER NOS, Number of times reported: 3 Sign: LOW BLOOD PRESSURE, Number of times reported: 3 Sign: LOW THYROXINE (T4), Number of times reported: 3 Sign: MAST CELL TUMOUR, Number of times reported: 3 Sign: MUSCLE WASTING, Number of times reported: 3 Sign: ORAL MASS, Number of times reported: 3 Sign: ORAL ULCERATION, Number of times reported: 3 Sign: OSTEOSARCOMA, Number of times reported: 3 Sign: PAPULE, Number of times reported: 3 Sign: PARALYSIS NOS, Number of times reported: 3 Sign: PARAPARESIS, Number of times reported: 3 Sign: PARESIS, Number of times reported: 3 Sign: PAWING, Number of times reported: 3 Sign: PEMPHIGUS, Number of times reported: 3 Sign: PICA NOS, Number of times reported: 3 Sign: PINNAL REDDENING, Number of times reported: 3 Sign: PNEUMONIA, Number of times reported: 3 Sign: POLYPHAGIA, Number of times reported: 3 Sign: POOR COAT CONDITION, Number of times reported: 3 Sign: PR-HEART, LESION(S), Number of times reported: 3 Sign: PROPRIOCEPTION LOSS, Number of times reported: 3 Sign: PRURITIC RASH, Number of times reported: 3 Sign: REDUCED RESPONSES, Number of times reported: 3 Sign: REGENERATIVE ANAEMIA, Number of times reported: 3 Sign: RESPIRATORY SIGNS, Number of times reported: 3 Sign: SEDATION, Number of times reported: 3 Sign: SHOCK, Number of times reported: 3 Sign: SLEEP DISTURBANCE NOS, Number of times reported: 3 Sign: SLEEPINESS - NEUROLOGICAL DISORDER, Number of times reported: 3 Sign: SOMNOLENCE, Number of times reported: 3 Sign: STIFFNESS LIMB, Number of times reported: 3 Sign: SWALLOWING DISORDER NOS, Number of times reported: 3 Sign: SWOLLEN FEET, Number of times reported: 3 Sign: SWOLLEN JOINT, Number of times reported: 3 Sign: TAIL PARESIS, Number of times reported: 3 Sign: TREMBLING, Number of times reported: 3 Sign: UNRESPONSIVE TO STIMULI, Number of times reported: 3 Sign: WEAK PULSE, Number of times reported: 3 Sign: ABDOMINAL EFFUSION, Number of times reported: 2 Sign: ABDOMINAL MASS, Number of times reported: 2 Sign: ABSCESS NOS, Number of times reported: 2

Sign: ANAL SAC DISORDER, Number of times reported: 2 Sign: APPETITE DISORDER NOS, Number of times reported: 2 Sign: ATTENTION-SEEKING BEHAVIOUR, Number of times reported: 2 Sign: AURAL HAEMATOMA, Number of times reported: 2 Sign: BILIRUBINURIA, Number of times reported: 2 Sign: BLOOD LOSS NOS, Number of times reported: 2 Sign: CARCINOMA NOS, Number of times reported: 2 Sign: CATARACT, Number of times reported: 2 Sign: CHOLANGIOHEPATITIS, Number of times reported: 2 Sign: COLD FEELING OF EXTREMITY, Number of times reported: 2 Sign: CONJUNCTIVITIS, Number of times reported: 2 Sign: CYANOSIS, Number of times reported: 2 Sign: DECREASED BLOOD UREA NITROGEN (BUN) OR CREATININE, Number of times reported: 2 Sign: DECREASED HEART RATE, Number of times reported: 2 Sign: DELAYED HEALING, Number of times reported: 2 Sign: DEPRESSED OCULAR REFLEX, Number of times reported: 2 Sign: DEPRESSED REFLEXES, Number of times reported: 2 Sign: DERMAL THICKENING, Number of times reported: 2 Sign: DIFFICULTY GOING UP/DOWN STAIRS, Number of times reported: 2 Sign: DIFFICULTY STANDING, Number of times reported: 2 Sign: DIGESTIVE TRACT STASIS, Number of times reported: 2 Sign: DISORDER OF RED BLOOD CELL NOS, Number of times reported: 2 Sign: DRY MUCOUS MEMBRANE, Number of times reported: 2 Sign: EAR DISCHARGE, Number of times reported: 2 Sign: EAR IRRITATION, Number of times reported: 2 Sign: ELEVATED PROTEIN: CREATININE RATIO, Number of times reported: 2 Sign: ELEVATED TRIGLYCERIDE, Number of times reported: 2 Sign: EPIDERMAL COLLARETTE, Number of times reported: 2 Sign: EXCESSIVE APPETITE, Number of times reported: 2 Sign: EXCESSIVE THIRST, Number of times reported: 2 Sign: FLACCID MUSCLES, Number of times reported: 2 Sign: FOCAL SEIZURE, Number of times reported: 2 Sign: FOLLICULITIS, Number of times reported: 2 Sign: FUNGAL SKIN INFECTION NOS, Number of times reported: 2 Sign: GALL BLADDER & BILE DUCT DISORDER NOS, Number of times reported: 2 Sign: GASTRITIS, Number of times reported: 2 Sign: GASTROENTERITIS, Number of times reported: 2 Sign: GENERALISED RED SPOT, Number of times reported: 2 Sign: GINGIVITIS, Number of times reported: 2 Sign: GRANULOMA, Number of times reported: 2 Sign: GUM DISORDER NOS, Number of times reported: 2 Sign: HAEMORRHAGE NOS, Number of times reported: 2 Sign: HEARING DECREASED, Number of times reported: 2

Sign: HORNER'S SYNDROME, Number of times reported: 2 Sign: HYPERALBUMINAEMIA, Number of times reported: 2 Sign: HYPERVENTILATION, Number of times reported: 2 Sign: HYPOALBUMINAEMIA, Number of times reported: 2 Sign: HYPOPHOSPHATAEMIA, Number of times reported: 2 Sign: IMPAIRED VOCALISATION, Number of times reported: 2 Sign: INCREASED BAND NEUTROPHILIA, Number of times reported: 2 Sign: INCREASED HEART RATE, Number of times reported: 2 Sign: INCREASED PERCENTAGE RETICULOCYTES, Number of times reported: 2 Sign: INCREASED URINE VOLUME, Number of times reported: 2 Sign: INJECTION SITE ABSCESS, Number of times reported: 2 Sign: INJECTION SITE INFECTION, Number of times reported: 2 Sign: INJECTION SITE SKIN SCALING, Number of times reported: 2 Sign: JAW DISORDER, Number of times reported: 2 Sign: LACK OF COORDINATION, Number of times reported: 2 Sign: LIMPNESS, Number of times reported: 2 Sign: LOCALISED SKIN REACTION, Number of times reported: 2 Sign: LOSS OF HEARING, Number of times reported: 2 Sign: LOSS OF VISION, Number of times reported: 2 Sign: LOSS OF VOLUNTARY MOVEMENT, Number of times reported: 2 Sign: LOW ALANINE AMINOTRANSFERASE (ALT), Number of times reported: 2 Sign: LOW SERUM ALKALINE PHOSPHATASE (SAP), Number of times reported: 2 Sign: LYMPHADENOPATHY, Number of times reported: 2 Sign: LYMPHOCYTOSIS, Number of times reported: 2 Sign: MELAENA, Number of times reported: 2 Sign: MOUTH ULCER, Number of times reported: 2 Sign: MUSCLE PAIN, Number of times reported: 2 Sign: MUSCLE SPASM NOS, Number of times reported: 2 Sign: NEUROLOGICAL SIGNS NOS, Number of times reported: 2 Sign: ORAL BLEEDING, Number of times reported: 2 Sign: ORAL CAVITY DISORDER NOS, Number of times reported: 2 Sign: OTHER BLOOD DISORDER NOS, Number of times reported: 2 Sign: PEELING SKIN, Number of times reported: 2 Sign: PERITONEAL FLUID, ABNORMAL NOS, Number of times reported: 2 Sign: PINNAL ERYTHEMA, Number of times reported: 2 Sign: PODODERMATITIS, Number of times reported: 2 Sign: POLLAKIURIA, Number of times reported: 2 Sign: PULMONARY NEOPLASM, Number of times reported: 2 Sign: PULMONARY OEDEMA, Number of times reported: 2 Sign: PYURIA, Number of times reported: 2 Sign: RECUMBENCY, Number of times reported: 2 Sign: REDUCED FAECAL OUTPUT, Number of times reported: 2 Sign: REGURGITATION, Number of times reported: 2

Sign: RESPIRATORY ARREST, Number of times reported: 2 Sign: RETINAL DETACHMENT, Number of times reported: 2 Sign: RIGIDITY OF LIMBS, Number of times reported: 2 Sign: RINGWORM, Number of times reported: 2 Sign: ROLLING, Number of times reported: 2 Sign: RUBBING, Number of times reported: 2 Sign: SALINE SLIDE AGGLUTINATION TEST, POSITIVE, Number of times reported: 2 Sign: SHALLOW BREATHING, Number of times reported: 2 Sign: SKIN ABSCESS, Number of times reported: 2 Sign: SKIN HAEMATOMA, Number of times reported: 2 Sign: SKIN NECROSIS, Number of times reported: 2 Sign: SKIN SWELLING, Number of times reported: 2 Sign: SKIN TEXTURAL CHANGE, Number of times reported: 2 Sign: SKIN TUMOUR NOS, Number of times reported: 2 Sign: SQUINTING, Number of times reported: 2 Sign: STRANGURIA, Number of times reported: 2 Sign: STRIDOR (UPPER RESPIRATORY; FOR LOWER RESPIRATORY SEE ALSO BRONCHIAL RALE), Number of times reported: 2 Sign: STROKE, Number of times reported: 2 Sign: SWOLLEN EYELID, Number of times reported: 2 Sign: SWOLLEN LIP, Number of times reported: 2 Sign: SYMPTOM NOS INVOLVING NEUROLOGICAL AND MUSCULAR SKELETAL SOCS, Number of times reported: 2 Sign: TAIL PARALYSIS, Number of times reported: 2 Sign: TEMPORARY BLINDNESS, Number of times reported: 2 Sign: THIRD EYELID PROTRUSION, Number of times reported: 2 Sign: UNABLE TO WALK, Number of times reported: 2 Sign: UNILATERAL PARESIS, Number of times reported: 2 Sign: UNWELL, Number of times reported: 2 Sign: URINARY TRACT DISORDER NOS, Number of times reported: 2 Sign: URINARY TRACT OBSTRUCTION/BLOCKAGE, Number of times reported: 2 Sign: UVEITIS, Number of times reported: 2 Sign: VASCULITIS, Number of times reported: 2 Sign: WIDE-BASE STANCE, Number of times reported: 2 Sign: ABDOMINAL CAVITY HAEMORRHAGE, Number of times reported: 1 Sign: ABNORMAL DIGITAL PULSE, Number of times reported: 1 Sign: ABNORMAL RED BLOOD CELL, Number of times reported: 1 Sign: ABNORMAL STOOL COLOURATION, Number of times reported: 1 Sign: ABNORMAL URINE ODOUR, Number of times reported: 1 Sign: ABNORMAL VISION, Number of times reported: 1 Sign: ACIDIC URINE, Number of times reported: 1 Sign: ADRENAL GLAND DISORDER NOS, Number of times reported: 1 Sign: AGONAL BREATHING, Number of times reported: 1 Sign: ALLERGIC PRURITUS, Number of times reported: 1

Sign: ALOPECIA GENERAL, Number of times reported: 1

Sign: ANAPHYLACTIC SHOCK, Number of times reported: 1 Sign: APPLICATION SITE ALOPECIA, Number of times reported: 1 Sign: APPLICATION SITE SCAB, Number of times reported: 1 Sign: ASTHMA, Number of times reported: 1 Sign: ATRIAL FIBRILLATION, Number of times reported: 1 Sign: BLADDER DISTENSION, Number of times reported: 1 Sign: BLEPHARITIS, Number of times reported: 1 Sign: BLOATED, Number of times reported: 1 Sign: BLOOD IN FAECES NOS, Number of times reported: 1 Sign: BRUISING, Number of times reported: 1 Sign: CALCULI, Number of times reported: 1 Sign: CARBON DIOXIDE HIGH, BLOOD, Number of times reported: 1 Sign: CARDIAC MURMUR, Number of times reported: 1 Sign: CARDIOMYOPATHY, Number of times reported: 1 Sign: CARDIORESPIRATORY ARREST, Number of times reported: 1 Sign: CENTRAL NERVOUS SYSTEM DEPRESSION, Number of times reported: 1 Sign: CENTRAL VESTIBULAR DISORDER, Number of times reported: 1 Sign: CERVICAL SPONDYLOPATHY, Number of times reported: 1 Sign: CHEMOSIS, Number of times reported: 1 Sign: CIRCULATORY COLLAPSE, Number of times reported: 1 Sign: COLITIS, Number of times reported: 1 Sign: COLOR, ABNORMAL, Number of times reported: 1 Sign: COMA, Number of times reported: 1 Sign: CONJUNCTIVAL OEDEMA, Number of times reported: 1 Sign: CONTAMINATION, FOREIGN OBJECT, Number of times reported: 1 Sign: CONVULSION, Number of times reported: 1 Sign: CRACKLES ON AUSCULTATION, Number of times reported: 1 Sign: CRANIAL NERVE DISORDER, Number of times reported: 1 Sign: CRYSTALLURIA, Number of times reported: 1 Sign: CYST NOS, Number of times reported: 1 Sign: DECREASED PERCENTAGE OF RETICULOCYTES, Number of times reported: 1 Sign: DECREASED PULSE OXYGENATION, Number of times reported: 1 Sign: DEHISCENCE, Number of times reported: 1 Sign: DENTAL CALCULUS, Number of times reported: 1 Sign: DENTAL DISEASE, Number of times reported: 1 Sign: DEPRESSION, Number of times reported: 1 Sign: DERMAL CYST(S), Number of times reported: 1 Sign: DERMAL NODULE, Number of times reported: 1 Sign: DESTRUCTIVE BEHAVIOUR, Number of times reported: 1 Sign: DIABETIC KETOACIDOSIS, Number of times reported: 1 Sign: DIFFICULTY EATING NOS, Number of times reported: 1 Sign: DISORDER OF GASTROINTESTINAL FLORA, Number of times reported: 1

Sign: DROOPY EAR, Number of times reported: 1

Sign: DRY COAT, Number of times reported: 1 Sign: DULLNESS, Number of times reported: 1 Sign: DUODENAL ULCER, Number of times reported: 1 Sign: DYSMETRIA, Number of times reported: 1 Sign: DYSPHAGIA, Number of times reported: 1 Sign: DYSURIA, Number of times reported: 1 Sign: EAR CANAL OEDEMA, Number of times reported: 1 Sign: EAR PAIN, Number of times reported: 1 Sign: EAR TWITCHING, Number of times reported: 1 Sign: ELEVATED CHOLESTEROL (TOTAL), Number of times reported: 1 Sign: ELEVATED LACTATE, Number of times reported: 1 Sign: ENLARGED KIDNEY(S), Number of times reported: 1 Sign: ENLARGED LIVER, Number of times reported: 1 Sign: ENLARGED THYROID GLAND, Number of times reported: 1 Sign: ENTERITIS, Number of times reported: 1 Sign: ENTROPION, Number of times reported: 1 Sign: ERUCTATION, Number of times reported: 1 Sign: ERYTHEMATOUS RASH, Number of times reported: 1 Sign: EXCESSIVE DEFENSIVE BEHAVIOUR, Number of times reported: 1 Sign: EXCITATION, Number of times reported: 1 Sign: EYE DISORDER NOS, Number of times reported: 1 Sign: EYELID ERYTHEMA, Number of times reported: 1 Sign: EYELID INFLAMMATION, Number of times reported: 1 Sign: FAINTING, Number of times reported: 1 Sign: FASCICULATION, Number of times reported: 1 Sign: FATIGUE, Number of times reported: 1 Sign: FIBROSARCOMA, Number of times reported: 1 Sign: FLATULENCE, BLOATING AND DISTENSION, Number of times reported: 1 Sign: FLUID IN ABDOMEN NOS, Number of times reported: 1 Sign: FLUID IN THORAX, Number of times reported: 1 Sign: FOOD REFUSAL, Number of times reported: 1 Sign: FURUNCULOSIS, Number of times reported: 1 Sign: GALL STONE, Number of times reported: 1 Sign: GASTRIC ULCER, Number of times reported: 1 Sign: GENERALISED RASH, Number of times reported: 1 Sign: GENERALISED SKIN REACTION, Number of times reported: 1 Sign: GENITAL TRACT LICKING, Number of times reported: 1 Sign: GINGIVAL DISORDER, Number of times reported: 1 Sign: GLAUCOMA, Number of times reported: 1 Sign: GLUCOSE INTOLERANCE, Number of times reported: 1 Sign: GREASY SKIN, Number of times reported: 1 Sign: HAEMATEMESIS, Number of times reported: 1 Sign: HAEMATOMA NOS, Number of times reported: 1

Sign: HAEMORRHAGIC BLADDER, Number of times reported: 1 Sign: HAIR CHANGE, Number of times reported: 1 Sign: HAIR MODIFICATION NOS, Number of times reported: 1 Sign: HEAD DOWN, Number of times reported: 1 Sign: HEART FAILURE, Number of times reported: 1 Sign: HEAVY BREATHING, Number of times reported: 1 Sign: HEPATITIS, Number of times reported: 1 Sign: HEPATOMEGALY, Number of times reported: 1 Sign: HIGH FREE THYROXINE (FT4), Number of times reported: 1 Sign: HIGH TRI-IODOTHYRONINE (T3), Number of times reported: 1 Sign: HIGH TRYPSIN-LIKE IMMUNOREACTIVITY (TLI), Number of times reported: 1 Sign: HISSING, Number of times reported: 1 Sign: HIVES, Number of times reported: 1 Sign: HYPEREXTENSION, Number of times reported: 1 Sign: HYPERKERATOSIS, Number of times reported: 1 Sign: HYPERPNOEA, Number of times reported: 1 Sign: HYPERSENSITIVITY NOS, Number of times reported: 1 Sign: HYPERSENSITIVITY REACTION, Number of times reported: 1 Sign: HYPERSENSITIVITY TO PAIN, Number of times reported: 1 Sign: HYPERTROPHIC CONCENTRIC CARDIOMYOPATHY, Number of times reported: 1 Sign: HYPERTROPHIC DILATED CARDIOMYOPATHY, Number of times reported: 1 Sign: HYPHAEMIA, Number of times reported: 1 Sign: HYPOREFLEXIA, Number of times reported: 1 Sign: HYPOSTHENURIA, Number of times reported: 1 Sign: HYPOTHYROIDISM, Number of times reported: 1 Sign: HYPOVOLAEMIC SHOCK, Number of times reported: 1 Sign: IMMUNE-MEDIATED POLYARTHRITIS, Number of times reported: 1 Sign: IMPAIRED CONSCIOUSNESS, Number of times reported: 1 Sign: INCOORDINATION, Number of times reported: 1 Sign: INCREASED BORBORYGMUS, Number of times reported: 1 Sign: INCREASED COAGULATION TIME, Number of times reported: 1 Sign: INCREASED RED BLOOD CELL COUNT, Number of times reported: 1 Sign: INCREASED SENSITIVITY TO LIGHT, Number of times reported: 1 Sign: INEFFECTIVE, ANALGESIA, Number of times reported: 1 Sign: INJECTION SITE BRUISING, Number of times reported: 1 Sign: INJECTION SITE HAIR CHANGE, Number of times reported: 1 Sign: INJECTION SITE IRRITATION, Number of times reported: 1 Sign: INJECTION SITE SCRATCHING, Number of times reported: 1 Sign: INJECTION SITE SEROUS DISCHARGE, Number of times reported: 1 Sign: INJECTION SITE THICKENING, Number of times reported: 1 Sign: INTERDIGITAL OEDEMA, Number of times reported: 1 Sign: INTUSSUSCEPTION, Number of times reported: 1 Sign: INVOLUNTARY MOVEMENT, Number of times reported: 1

Sign: IRIS DISORDER, Number of times reported: 1 Sign: IRON DEFICIENCY ANAEMIA, Number of times reported: 1 Sign: JAW PAIN, Number of times reported: 1 Sign: JOINT EFFUSION, Number of times reported: 1 Sign: JOINT OEDEMA, Number of times reported: 1 Sign: JOINT PAIN, Number of times reported: 1 Sign: JOINT STIFFNESS, Number of times reported: 1 Sign: KIDNEY ATROPHY, Number of times reported: 1 Sign: LACK OF EFFICACY (ECTOPARASITE) - FLEA, Number of times reported: 1 Sign: LACK OF EFFICACY (VIRUS) - NOS, Number of times reported: 1 Sign: LACK OF HAIR REGROWTH, Number of times reported: 1 Sign: LACK OF RESPONSE TO OWNER, Number of times reported: 1 Sign: LENS LUXATION, Number of times reported: 1 Sign: LICK GRANULOMA, Number of times reported: 1 Sign: LIGAMENT RUPTURE, Number of times reported: 1 Sign: LIP LICKING, Number of times reported: 1 Sign: LIP SMACKING, Number of times reported: 1 Sign: LIVER FAILURE, Number of times reported: 1 Sign: LIVER TUMOUR, Number of times reported: 1 Sign: LOCALISED OEDEMA (NOT APPLICATION SITE), Number of times reported: 1 Sign: LOSS OF SMELL, Number of times reported: 1 Sign: LOW LIVER ENZYMES, Number of times reported: 1 Sign: LOW PANCREATIC ENZYMES, Number of times reported: 1 Sign: LUNG COLLAPSE, Number of times reported: 1 Sign: LUNG TUMOUR, Number of times reported: 1 Sign: LYMPHOEDEMA, Number of times reported: 1 Sign: MALODOUR, Number of times reported: 1 Sign: MAMMARY GLAND DISORDER NOS, Number of times reported: 1 Sign: MAMMARY GLAND NEOPLASM NOS, Number of times reported: 1 Sign: MISCELLANEOUS EATING DISORDER NOS, Number of times reported: 1 Sign: MUCOCUTANEOUS ULCER, Number of times reported: 1 Sign: MUCOUS STOOL, Number of times reported: 1 Sign: MUCUS IN EYE, Number of times reported: 1 Sign: MULTIPLE MYELOMA, Number of times reported: 1 Sign: MURMUR, Number of times reported: 1 Sign: MUSCLE CONTRACTURE, Number of times reported: 1 Sign: MUSCLE STIFFNESS, Number of times reported: 1 Sign: MUSCULOSKELETAL NEOPLASM NOS, Number of times reported: 1 Sign: MYASTHENIA GRAVIS, Number of times reported: 1 Sign: MYELOPATHY NOS, Number of times reported: 1 Sign: MYOCLONIC JERK, Number of times reported: 1 Sign: MYOSITIS, Number of times reported: 1 Sign: NECK PAIN - NEUROLOGICAL, Number of times reported: 1

Sign: NECROPSY PERFORMED, Number of times reported: 1 Sign: NEUROLOGICAL DISORDER NOS, Number of times reported: 1 Sign: NEUROPATHY NOS, Number of times reported: 1 Sign: NOT SLEEPING, Number of times reported: 1 Sign: OCULAR BURN, Number of times reported: 1 Sign: OEDEMA OF THE EXTREMITIES, Number of times reported: 1 Sign: OFF FOOD, Number of times reported: 1 Sign: OLIGURIA, Number of times reported: 1 Sign: OTHER EAR DISORDER NOS, Number of times reported: 1 Sign: OTIC HAEMATOMA, Number of times reported: 1 Sign: OTITIS MEDIA, Number of times reported: 1 Sign: PADDLING, Number of times reported: 1 Sign: PALPEBRAL OEDEMA, Number of times reported: 1 Sign: PANCYTOPENIA, Number of times reported: 1 Sign: PAPULAR RASH, Number of times reported: 1 Sign: PARAESTHESIA GENERALISED, Number of times reported: 1 Sign: PARAPLEGIA, Number of times reported: 1 Sign: PARONYCHIA, Number of times reported: 1 Sign: PERIORBITAL OEDEMA, Number of times reported: 1 Sign: PERIPHERAL NEUROPATHY, Number of times reported: 1 Sign: PINNAL IRRITATION, Number of times reported: 1 Sign: PITTING OEDEMA, Number of times reported: 1 Sign: POLYARTHRITIS, Number of times reported: 1 Sign: POLYCYTHAEMIA, Number of times reported: 1 Sign: PREMATURE VENTRICULAR CONTRACTIONS, Number of times reported: 1 Sign: PR-KIDNEY(S), LESION(S), Number of times reported: 1 Sign: PROLONGED BLEEDING NOS, Number of times reported: 1 Sign: PR-THYROID, LESION(S), Number of times reported: 1 Sign: PULMONARY METASTASES, Number of times reported: 1 Sign: PULMONARY THROMBOEMBOLISM, Number of times reported: 1 Sign: QUADRIPLEGIA, Number of times reported: 1 Sign: RECTAL MASS, Number of times reported: 1 Sign: RED BLOOD CELL DISORDER, Number of times reported: 1 Sign: REDUCED LEVEL OF CONSCIOUSNESS, Number of times reported: 1 Sign: RENAL TUBULAR DISORDER, Number of times reported: 1 Sign: RESPIRATORY DEPRESSION, Number of times reported: 1 Sign: RESPIRATORY FAILURE, Number of times reported: 1 Sign: RESPIRATORY TRACT DISORDER NOS, Number of times reported: 1 Sign: RETINAL HAEMORRHAGE, Number of times reported: 1 Sign: RHINITIS, Number of times reported: 1 Sign: RIGIDITY, Number of times reported: 1 Sign: SCALY CONDITION NOS, Number of times reported: 1 Sign: SCLERAL HAEMORRHAGE, Number of times reported: 1

Sign: SEMI-CONSCIOUS, Number of times reported: 1 Sign: SENSATION LOSS, Number of times reported: 1 Sign: SEPTICAEMIA, Number of times reported: 1 Sign: SEROMA, Number of times reported: 1 Sign: SHIVERING, Number of times reported: 1 Sign: SINUS DISORDER NOS, Number of times reported: 1 Sign: SKIN AND/OR APPENDAGE NEOPLASM NOS, Number of times reported: 1 Sign: SKIN DRYNESS, Number of times reported: 1 Sign: SKIN HYPERAEMIA, Number of times reported: 1 Sign: SKIN HYPERPLASIA, Number of times reported: 1 Sign: SKIN SARCOMA NOS, Number of times reported: 1 Sign: SLOW REFLEXES, Number of times reported: 1 Sign: SMALL LIVER, Number of times reported: 1 Sign: SNORING, Number of times reported: 1 Sign: SPINDLE CELL TUMOUR, Number of times reported: 1 Sign: SPLENOMEGALY, Number of times reported: 1 Sign: SPONDYLOSIS, Number of times reported: 1 Sign: STERNOABDOMINAL RECUMBENCY, Number of times reported: 1 Sign: STOMATITIS, Number of times reported: 1 Sign: STUPOR, Number of times reported: 1 Sign: SUNKEN EYES, Number of times reported: 1 Sign: SWOLLEN LYMPH NODE, Number of times reported: 1 Sign: SWOLLEN MUZZLE, Number of times reported: 1 Sign: SYSTEMIC FUNGAL INFECTION, Number of times reported: 1 Sign: TARRY OR BLACK STOOL, Number of times reported: 1 Sign: TEMPORARY DEAFNESS, Number of times reported: 1 Sign: TENDINITIS, Number of times reported: 1 Sign: TENDON INJURY, Number of times reported: 1 Sign: THIRD EYELID PROLAPSE, Number of times reported: 1 Sign: THORACIC CAVITY DISORDER NOS, Number of times reported: 1 Sign: THROMBOCYTOSIS, Number of times reported: 1 Sign: TIREDNESS, Number of times reported: 1 Sign: TONGUE DISORDER NOS, Number of times reported: 1 Sign: TONGUE PROTRUSION, Number of times reported: 1 Sign: TOOTH DISORDER, Number of times reported: 1 Sign: TOOTH LOSS, Number of times reported: 1 Sign: TORN LIGAMENT, Number of times reported: 1 Sign: TRACHEAL AND LARYNGEAL DISORDER NOS, Number of times reported: 1 Sign: TREMOR OF LIMB, Number of times reported: 1 Sign: UNCLASSIFIABLE ADVERSE EVENT, Number of times reported: 1 Sign: UNUSUAL STOOL COLOUR, Number of times reported: 1 Sign: URINARY RETENTION, Number of times reported: 1 Sign: URINATION RELATED TO CONVULSION, Number of times reported: 1

Sign: URINE LEAKAGE, Number of times reported: 1 Sign: VENTRICULAR ARRHYTHMIA, Number of times reported: 1 Sign: VITAMIN DEFICIENCY, Number of times reported: 1 Sign: VITAMIN DISORDER, Number of times reported: 1 Sign: VOICE ALTERATION, Number of times reported: 1

Species: Cat Route of Administration: u

Sign: DIARRHOEA, Number of times reported: 12 Sign: LACK OF EFFICACY - NOS, Number of times reported: 12 Sign: VOMITING, Number of times reported: 9 Sign: WEIGHT LOSS, Number of times reported: 8 Sign: DEATH, Number of times reported: 7 Sign: DECREASED APPETITE, Number of times reported: 6 Sign: LETHARGY, Number of times reported: 6 Sign: NOT EATING, Number of times reported: 6 Sign: SCRATCHING, Number of times reported: 6 Sign: SKIN SCAB, Number of times reported: 6 Sign: ANOREXIA, Number of times reported: 5 Sign: BEHAVIOURAL DISORDER NOS, Number of times reported: 5 Sign: NOT DRINKING, Number of times reported: 5 Sign: PACING, Number of times reported: 5 Sign: ALOPECIA, Number of times reported: 4 Sign: DEATH BY EUTHANASIA, Number of times reported: 4 Sign: ELEVATED RENAL PARAMETERS, Number of times reported: 4 Sign: RENAL DISORDER NOS, Number of times reported: 4 Sign: VOCALISATION, Number of times reported: 4 Sign: ATAXIA, Number of times reported: 3 Sign: DISORIENTATION, Number of times reported: 3 Sign: EXCESSIVE CHEWING, LICKING AND/OR GROOMING, Number of times reported: 3 Sign: HIDING, Number of times reported: 3 Sign: LAMENESS, Number of times reported: 3 Sign: LOSS OF VISION, Number of times reported: 3 Sign: LYING DOWN, Number of times reported: 3 Sign: ANAEMIA NOS, Number of times reported: 2 Sign: APPETITE LOSS, Number of times reported: 2 Sign: CIRCLING - BEHAVIOURAL DISORDER, Number of times reported: 2 Sign: DEHYDRATION, Number of times reported: 2 Sign: DILATED PUPILS, Number of times reported: 2 Sign: FACIAL PRURITUS, Number of times reported: 2 Sign: FEVER, Number of times reported: 2 Sign: GAIT ABNORMALITY, Number of times reported: 2 Sign: HAIR LOSS NOS, Number of times reported: 2 Sign: HEART MURMUR, Number of times reported: 2

Sign: HIND LIMB ATAXIA, Number of times reported: 2 Sign: HIND LIMB PARESIS, Number of times reported: 2 Sign: INCREASED APPETITE, Number of times reported: 2 Sign: ITCHING, Number of times reported: 2 Sign: LESS SOCIAL, Number of times reported: 2 Sign: MUSCULOSKELETAL DISORDER NOS, Number of times reported: 2 Sign: NAUSEA, Number of times reported: 2 Sign: NOT HIMSELF/HERSELF, Number of times reported: 2 Sign: PARTIAL LACK OF EFFICACY, Number of times reported: 2 Sign: SKIN LESION NOS, Number of times reported: 2 Sign: TWITCHING, Number of times reported: 2 Sign: WALKING DIFFICULTY, Number of times reported: 2 Sign: ABDOMINAL MASS, Number of times reported: 1 Sign: AGGRESSION, Number of times reported: 1 Sign: ANXIETY, Number of times reported: 1 Sign: APPLICATION SITE HAIR LOSS, Number of times reported: 1 Sign: ARCHED BACK, Number of times reported: 1 Sign: ARTHRITIS, Number of times reported: 1 Sign: ASCITES, Number of times reported: 1 Sign: BALANCE IMPAIRED, Number of times reported: 1 Sign: BITING -AGGRESSION, Number of times reported: 1 Sign: BLINDNESS, Number of times reported: 1 Sign: BLOOD IN FAECES NOS, Number of times reported: 1 Sign: BUMPING INTO WALLS, Number of times reported: 1 Sign: CARDIAC FAILURE, Number of times reported: 1 Sign: CARDIOMYOPATHY, Number of times reported: 1 Sign: CHRONIC PANCREATITIS, Number of times reported: 1 Sign: DECREASED ACTIVITY, Number of times reported: 1 Sign: DECREASED BOWEL MOVEMENTS, Number of times reported: 1 Sign: DECREASED DRINKING, Number of times reported: 1 Sign: DERMATITIS, Number of times reported: 1 Sign: DIABETES MELLITUS, Number of times reported: 1 Sign: DRINKING A LOT, Number of times reported: 1 Sign: DROOLING, Number of times reported: 1 Sign: DROWSINESS - SYSTEMIC DISORDER, Number of times reported: 1 Sign: ELEVATED ALANINE AMINOTRANSFERASE (ALT), Number of times reported: 1 Sign: ELEVATED CREATININE, Number of times reported: 1 Sign: ELEVATED GLOBULINS, Number of times reported: 1 Sign: ELEVATED LIVER ENZYMES, Number of times reported: 1 Sign: ELEVATED SERUM ALKALINE PHOSPHATASE (SAP), Number of times reported: 1 Sign: ELEVATED SYMMETRICAL DIMETHYLARGININE (SDMA), Number of times reported: 1 Sign: ERUPTION, Number of times reported: 1 Sign: EYE DISORDER NOS, Number of times reported: 1

Sign: EYE ITCHING, Number of times reported: 1 Sign: FALLING, Number of times reported: 1 Sign: FREQUENT URINATION, Number of times reported: 1 Sign: GAGGING, Number of times reported: 1 Sign: GENERAL ILLNESS, Number of times reported: 1 Sign: GROWLING, Number of times reported: 1 Sign: HEAD BOBBING, Number of times reported: 1 Sign: HEAD DOWN, Number of times reported: 1 Sign: HEAD TILT - NEUROLOGICAL DISORDER, Number of times reported: 1 Sign: HEARING DECREASED, Number of times reported: 1 Sign: HEAVY BREATHING, Number of times reported: 1 Sign: HIGH BLOOD PRESSURE, Number of times reported: 1 Sign: HIND LIMB PARALYSIS, Number of times reported: 1 Sign: HOT SPOT (PYOTRAUMATIC DERMATITIS), Number of times reported: 1 Sign: IMPAIRED VOCALISATION, Number of times reported: 1 Sign: INAPPETENCE, Number of times reported: 1 Sign: INJECTION SITE HAIR LOSS, Number of times reported: 1 Sign: INJECTION SITE LESION, Number of times reported: 1 Sign: INJECTION SITE SWELLING, Number of times reported: 1 Sign: INTESTINAL DISORDER NOS, Number of times reported: 1 Sign: LABOURED BREATHING, Number of times reported: 1 Sign: LACK OF RESPONSE TO OWNER, Number of times reported: 1 Sign: LEUCOCYTOSIS NOS, Number of times reported: 1 Sign: LIMPING, Number of times reported: 1 Sign: LOCALISED ITCHING, Number of times reported: 1 Sign: LOCALISED PAIN NOS, Number of times reported: 1 Sign: LOOSE STOOL, Number of times reported: 1 Sign: LOSS OF SMELL, Number of times reported: 1 Sign: LYMPHOCYTOSIS, Number of times reported: 1 Sign: MISCELLANEOUS EATING DISORDER NOS, Number of times reported: 1 Sign: MONOCYTOSIS, Number of times reported: 1 Sign: MUSCLE ATROPHY, Number of times reported: 1 Sign: MUSCLE SPASM NOS, Number of times reported: 1 Sign: MUSCLE WEAKNESS NOS, Number of times reported: 1 Sign: NEUROLOGICAL DISORDER NOS, Number of times reported: 1 Sign: NEUTROPHILIA, Number of times reported: 1 Sign: NOT SLEEPING, Number of times reported: 1 Sign: OEDEMA OF THE EXTREMITIES, Number of times reported: 1 Sign: OTHER ABNORMAL TEST RESULT NOS, Number of times reported: 1 Sign: PANCREATITIS, Number of times reported: 1 Sign: PERICARDIAL EFFUSION, Number of times reported: 1 Sign: PLEURAL EFFUSION, Number of times reported: 1 Sign: PRURITUS, Number of times reported: 1

Sign: RASH, Number of times reported: 1 Sign: RED EYE, Number of times reported: 1 Sign: REDDENING OF THE SKIN, Number of times reported: 1 Sign: SEIZURE NOS, Number of times reported: 1 Sign: SHAKING, Number of times reported: 1 Sign: SICKNESS, Number of times reported: 1 Sign: SKIN AND TISSUE INFECTION NOS, Number of times reported: 1 Sign: SKIN LUMP, Number of times reported: 1 Sign: SKIN SORE, Number of times reported: 1 Sign: SLEEP DISTURBANCE NOS, Number of times reported: 1 Sign: SLEEPINESS - SYSTEMIC DISORDER, Number of times reported: 1 Sign: SNEEZING, Number of times reported: 1 Sign: SQUINTING, Number of times reported: 1 Sign: STARING, Number of times reported: 1 Sign: SYSTEMIC DISORDER NOS, Number of times reported: 1 Sign: TREMOR, Number of times reported: 1 Sign: TREMOR OF LIMB, Number of times reported: 1 Sign: UNABLE TO RISE, Number of times reported: 1 Sign: UNABLE TO WALK, Number of times reported: 1 Sign: URINARY TRACT DISORDER NOS, Number of times reported: 1 Sign: WEIGHT GAIN, Number of times reported: 1 Sign: WOUND, Number of times reported: 1

Species: Dog Route of Administration: s

Sign: ANOREXIA, Number of times reported: 1 Sign: LETHARGY, Number of times reported: 1

Species: Human Route of Administration: i

Sign: ACCIDENTAL EXPOSURE, Number of times reported: 1 Sign: INJECTION SITE BLEEDING, Number of times reported: 1 Sign: LACERATION, Number of times reported: 1

Species: Human Route of Administration: O

Sign: EYE IRRITATION, Number of times reported: 1

Species: Human Route of Administration: T

Sign: DIARRHOEA, Number of times reported: 1

Sign: DIZZINESS, Number of times reported: 1

Species: Human Route of Administration: u

Sign: PUNCTURE WOUND, Number of times reported: 24

Sign: ACCIDENTAL EXPOSURE, Number of times reported: 9 Sign: INJECTION SITE BLEEDING, Number of times reported: 5 Sign: INJECTION SITE PAIN, Number of times reported: 4 Sign: ABRASION, Number of times reported: 1 Sign: INJECTION SITE ERYTHEMA, Number of times reported: 1 Sign: INJECTION SITE PRURITUS, Number of times reported: 1 Sign: INJECTION SITE TINGLING, Number of times reported: 1 Sign: LOCALISED OEDEMA (NOT APPLICATION SITE), Number of times reported: 1 Sign: LOCALISED PAIN NOS, Number of times reported: 1 Sign: NUMBNESS, Number of times reported: 1 Sign: PAIN NOS, Number of times reported: 1 Sign: TINGLING SENSATION, Number of times reported: 1

Species: Lynx Route of Administration: s

Sign: LACK OF EFFICACY - NOS, Number of times reported: 1 Sign: TOOTH DISORDER, Number of times reported: 1

Species: Not specified Route of Administration: M

Sign: UNDERFILLING, CONTAINER, Number of times reported: 24 Sign: UNDERFILLING, PACKAGE, Number of times reported: 11 Sign: CLOSURE, ABNORMAL, Number of times reported: 3 Sign: CONTAINERS, DAMAGED, Number of times reported: 3 Sign: UNDERFILLING, VIALS, Number of times reported: 3 Sign: CLOSURE, MISSING, Number of times reported: 2 Sign: COLOR, ABNORMAL, Number of times reported: 2 Sign: CONTAINERS, ABNORMAL, Number of times reported: 2 Sign: CONTAINERS, LEAKING, Number of times reported: 2 Sign: DIFFICULTY OF USE, Number of times reported: 2 Sign: MISSING LABELS, Number of times reported: 1 Sign: PRODUCT LABEL INFORMATION INCORRECT, Number of times reported: 1 Sign: SEAL, ABNORMAL, Number of times reported: 1 Sign: STOPPER, ABNORMAL, Number of times reported: 1 Sign: VIALS, ABNORMAL, Number of times reported: 1 Sign: VIALS, LEAKING, Number of times reported: 1

Species: Other Route of Administration: s

Sign: LACK OF EFFICACY - NOS, Number of times reported: 1