For Animal Use Only

SCHEDULING STATUS:

S3

PROPRIETARY NAME (AND DOSAGE FORM):

NOROCARP INJECTION FOR DOGS

COMPOSITION:

The injection contains a solution of 50 mg Carprofen per ml (5 % m/v)

PHARMACOLOGICAL CLASSIFICATION:

C 3.1.2.1 Non-selective COX_2 inhibitors.

PHARMACOLOGICAL ACTION:

Carprofen is a non-steroidal anti-inflammatory drug (NSAID) with characteristic analgesic and antipyretic activity. Carprofen is a derivative of phenyl propionic acid and a member of the aryl propionic acid class of NSAIDs.

The exact mechanism of action of carprofen has not yet been established but inhibition of prostaglandin synthesis accounts for at least part of its mechanism of action. Carprofen is a moderately potent inhibitor of Phospholipase A2 and a reversible inhibitor of cyclo-oxygenase (COX). Carprofen has been shown to inhibit the release of inflammatory mediators such as prostaglandins in acute polymorphonuclear leukocytes and chronic inflammatory reactions. Carprofen also demonstrates modulatory effects on both humoral and cellular immune responses. It inhibits the production of osteoclast-activating factor (OAF), PGE_1 and PGE_2 by means of the inhibitory effects on prostaglandin synthesis.

The absorption of carprofen by subcutaneous injection is rapid. The volume of distribution is small with the highest medicine concentrations occurring in plasma. Ratios of tissue to plasma concentrations are less than 1 which is consistent with the 99 % binding of the carprofen to plasma proteins. Pharmacokinetic data indicate that the mean elimination half-life is approximately 11,7 hours.

The main metabolic pathway for carprofen is conjugation of the carboxylic group with glucuronic acid. This reaction is catalysed by UDP-glucuronosyltransferases (UGTs) and leads to the formation of two

1-Ol-acyl-ß-glucuronide diastereoisomers (R-CPF and S-CPF glucuronides). These UGTs are abundant in the liver, and it is assumed that biotransformation mainly takes place in this organ. Carprofen is eliminated primarily by bio-transformation in the liver. Biliary secretion followed by excretion in the faeces accounts for 60 – 70 % of the administered dose. The excreted carprofen is present in the bile mainly as the ester glucuronide of carprofen or as the ether glucuronide of the two phenolic metabolites of carprofen.

Some enterohepatic circulation of the medicine is observed.

Target Species:

Dogs

INDICATIONS:

NOROCARP INJECTION FOR DOGS is indicated for control of post-operative pain and inflammation following orthopaedic and soft tissue surgery in dogs.

CONTRAINDICATIONS:

NOROCARP INJECTION FOR DOGS is contraindicated in known cases of hypersensitivity to carprofen.

NOROCARP INJECTION FOR DOGS is not recommended for use in dogs with bleeding disorders, as safety has not yet been established in dogs with these disorders.

Do not use in cats.

WARNINGS AND SPECIAL PRECAUTIONS:

Strict accuracy of diagnosis and close veterinary surveillance are imperative in dogs with clinical sign indicative of gastro-intestinal disease and in dogs suffering from impaired hepatic function.

As a class, cyclo-oxygenase inhibitory non-steroidal anti-inflammatory drugs (NSAIDs) may be associated with gastro-intestinal and renal toxicity. The most frequently reported effects have been mild gastro-intestinal signs. Events involving suspected renal, haematological, neurological, dermatological and hepatic effects have also been reported. Patients at greatest risk for renal toxicity are those on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction.

Prior to administration of NOROCARP INJECTION FOR DOGS or other NSAIDs to some patients, such a geriatric dog, a physical examination should be conducted and laboratory tests to establish

haematological and serum biochemical baseline data. Periodic monitoring may be appropriate in certain patients. Owners should be advised to watch for signs of medicine intolerance. Dogs receiving NOROCARP INJECTION FOR DOGS should be observed for signs such as inappetence, vomiting, diarrhoea, melaena, polyuria, polydipsia, anaemia, jaundice, lethargy, ataxia, seizure or behavioural changes. Susceptibility to medicine-associated adverse effects varies with the individual patient. The side effects of this medicine class, in rare situations, may be serious and if corrective action is not taken may result in hospitalization or even fatal outcomes.

The safe use of NOROCARP INJECTION FOR DOGS during pregnancy and lactation has not yet been established.

INTERACTIONS:

Concurrent use with other NSAIDS and corticosteroids should be avoided or closely monitored.

DOSAGE AND DIRECTIONS FOR USE:

NOROCARP INJECTION FOR DOGS is to be administered subcutaneously.

A dose rate of 4,4 mg carprofen/kg body mass/day (approximately 1 ml per 11,4 kg body mass) is recommended to be given ± 2 hours prior to the commencement of surgery and thereafter once daily as required.

Duration of treatment will be dependent upon the response seen. Long-term treatment should be under regular veterinary supervision.

SIDE EFFECTS:

NOROCARP INJECTION FOR DOGS may cause the following side effects:

Gastro-intestinal tract - vomiting, diarrhoea, inappetence, melaena, haematosis, gastro-intestinal ulceration.

Behavioural – sedation, lethargy, hyperactivity, restlessness.

Hepatic – inappetence, vomiting, jaundice, acute hepatic toxicity, hepatic enzyme elevation, abnormal liver function test(s), hyperbilirubinemia, hyperbilirubinuria, hypoalbuminemia. Approximately one-third of hepatic reports were in Labrador retrievers.

Renal – Haematuria, polyuria, polydipsia, urinary incontinence, urinary tract infection, azotaemia, acute renal failure, tubular abnormalities including acute tubular necrosis, renal acidosis, glucosuria.

Neurological – ataxia, paresis, paralysis, seizures, vestibular signs.

Haematological – Immune-mediated haemolytic anaemia, immune-mediated thrombocytopaenia, blood loss anaemia.
Dermatological – Pruritis, increased shedding, alopecia, pyotraumatic moist dermatitis (hot spots), necrotizing panniculitis/vasculitis, ventral ecchymosis.
Immunological or hypersensitivity – facial swelling, hives, erythema.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See Side effects and Warnings and special precautions.
Treatment is symptomatic and supportive.

IDENTIFICATION:

NOROCARP INJECTION FOR DOGS is a clear solution in an amber glass vial.

PRESENTATION:

NOROCARP INJECTION FOR DOGS is presented in a 20 ml multidose amber vial.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.
Use within 28 days after the first withdrawal.
KEEP OUT OF REACH OF CHILDREN, ANIMALS AND UNINFORMED PERSONS.

REGISTRATION NUMBER:

02/3.1/15

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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