Pardale-V™

tablets for dogs



Marketing authorisation holder:

Dechra Limited,

Snaygill Industrial Estate,

Keighley Road, Skipton,

North Yorkshire,

BD23 2RW, United Kingdom

Manufacturer responsible for batch release:

Dales Pharmaceuticals Limited,

Snaygill Industrial Estate,

Keighley Road, Skipton,

North Yorkshire,

BD23 2RW, United Kingdom

Name of the veterinary medicinal product: Pardale-V oral tablets for dogs Statement of the active substance and other ingredients: 1 tablet contains:

Active substances: Paracetamol 400 mg, Codeine phosphate hemihydrate 9 mg White, flat tablets with a bevelled edge and a break line.

Indication: For analgesic therapy in the dogs only. The product is indicated for acute pain of traumatic origin, as a complementary treatment in pain associated with other conditions, and post-operative analgesia.

Contraindications: Do not exceed the stated dose or the duration of treatment. Do not administer other NSAIDs concurrently or within 24 hours of each other. Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, or where there is evidence of blood dyscrasia or hypersensitivity to the product.

Do not use this preparation for cats.

Adverse reactions: Occasional constipation may occur due to codeine content. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species: Dogs.

Dosage, route and method of administration: For oral administration.

1 tablet per 12 kg body weight every 8 hours.

Small dogs (up to 6 kg body weight): ½ tablet every 8 hours. Medium dogs (6-18 kg body weight): ½-1½ tablets every 8 hours.

Large dogs (18-42 kg body weight): 11/2-31/2 tablets every 8 hours.

Treat for a maximum of 5 days.

Withdrawal period: Not applicable.

Special storage precautions: Keep out of the sight and reach of children. Do not store above 25°C. Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Special warnings:

Special warnings for each target species:

Seek veterinary advice if the treated condition does not improve or worsens during treatment. NSAIDs can cause inhibition of phagocytosis and hence, in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

Special precautions for use in animals:

Use in animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.

Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

User warnings:

Wash hands after use.

Use during pregnancy or lactation:

There are no known contraindications for use during pregnancy.

Interaction with other medicinal products and other forms of interaction:

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes):

Immediately seek the advice of a veterinary surgeon showing them the package leaflet. Carry out lavage and treat with intravenous injection of acetylcysteine (200 mg/ml) at a rate of 140 mg/kg every 6 hours for 7 treatments. Ascorbic acid (30 mg/kg) should also be given orally with each dose of acetylcysteine. If necessary, instigate fluid therapy using Ringer's or bicarbonate solution.

Treat for codeine overdose with injection of naloxone (1.0 mg/kg) repeated as necessary. Provide oxygen support.

Incompatibilities:

None known.

<u>Special precautions for the disposal of unused product or waste materials</u>; Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Date on which the package leaflet was last approved: January 2016

Other information: For animal treatment only.

Vm 10434/4034 NFA-VPS Non-Food Animal Medicine - Veterinarian, Pharmacist, Suitably Qualified Person

Containers of 100 or 500 tablets. Not all pack sizes may be marketed.

Local representative:

Dechra Veterinary Products Limited,

Sansaw Business Park,

Hadnall,

Shrewsbury,

Shropshire,

SY4 4AS, UK

