Prednidale

5 mg Tablets

UK

Presentation:

1 tablet contains: Active substance: Prednisolone 5 mg

White, circular flat-faced tablets.

Indications:

For the treatment of inflammatory and allergic diseases, including some autoimmune diseases and some neoplastic conditions in cats and dogs. Inflammatory, allergic and autoimmune processes may be involved in cutaneous, alimentary, respiratory, musculo-skeletal and haematological manifestations of disease.

Dosage and administration:

For oral administration only.

Dose: Dogs and cats: 0.1 - 2.0 mg prednisolone per kg body weight per day. The tablets are divisible.

The lowest effective dose must be used. These tablets are not appropriate when dosing cats and small dogs at the lower recommended dosage rates and another tablet strength may be required.

Treatment should not be withdrawn suddenly. A gradual reduction of dosage is recommended.

Dogs should be dosed in the morning and cats should be dosed at night to coincide with the endogenous cortisol peak.

A single administration may be sufficient for some conditions such as anaphylaxis. For more general treatment, administration for between one and three weeks at the above dosage levels may be required.

Dosage levels should be monitored carefully to ensure that the lowest effective dose is used.

Alternate-day therapy should be implemented to control symptoms if possible, to minimise the risk of adrenal insufficiency. Higher dose levels may be used in animals with tumours responsive to corticosteroid therapy. In these cases, the dosage level is related to the surface area of the animal and dose levels of between 20 mg per m^2 and 60 mg per m^2 have been found to be useful. The potential risks associated with these high dose levels should be assessed before commencing treatment.

Gloves should be worn to administer the product and you should wash hands immediately after administration of the product.

Contraindications and warnings: For animal treatment only.

Do not use in pregnant animals, those suffering from diabetes mellitus, in animals with renal insufficiency or those with corneal ulceration.

Do not use in animals being vaccinated with products containing live organisms. Treatment may render concurrent vaccination inoperative.

Appropriate therapy should be instituted in animals with concurrent bacterial infections. Use of corticosteroids may exacerbate viral infections. Prolonged use at high dose levels may result in undesirable effects.

Do not withdraw corticosteroid therapy suddenly.

Signs of overdosage should be treated symptomatically. Serum electrolytes should be monitored.

Consideration should be given to the use of antimicrobials due to the potential suppression of the immune system. Corticosteroids, including prednisolone, have a wide range of effects.

Polydipsia, polyuria and polyphagia may develop, particularly during the early stage of therapy. In the longer term, iatrogenic Cushing's disease may develop.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Administration of single high doses are generally tolerated well, but medium to long term use may provoke reactions. Corticosteroid therapy may lead to increased time in the healing of wounds and to a reduction in the ability of the body to resist infection. Appropriate anti-infective therapy may be required.

Pharmacologically active dose levels may lead to atrophy of the adrenal cortex, resulting in adrenal insufficiency. This may become apparent particularly after withdrawal of corticosteroid treatment. Adrenal insufficiency may be minimised by institution of alternate-day therapy, if practical. The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency.

Corticosteroids are not recommended for use in pregnant animals. Studies in laboratory animals have shown that administration during early pregnancy may cause foetal abnormalities. Administration during the later stages of pregnancy may cause abortion or early parturition.

Insignificant amounts of prednisolone are generally eliminated in the milk of lactating animals, and therefore such use is not contraindicated.

Gastrointestinal ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs (NSAIDs).

Regular veterinary re-evaluation of animals on prolonged courses of prednisolone is recommended.

Special storage precautions: Keep out of the reach and sight of children.

Do not store above 25˚C.

Store in tightly closed original container.

Store in a dry place.

Disposal:

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Legal category:

POM-V Prescription Only Medicine - Veterinarian

To be supplied only on veterinary prescription.

Package quantities:

Plastic pots containing 1000 tablets.

Marketing authorisation number:

Vm 10434/4009

Date of preparation:

11.12.2012

Marketing authorisation holder:

Dechra Limited, Dechra House,
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UK: Vm 10434/4009 POM-V Prescription Only Medicine - Veterinarian

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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