SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Prednidale 5 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient
Prednisolone 5 mg/tablet

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
White, circular, flat faced tablets with a breakline and PL5 imprinted on one face and DP on the reverse.
No data has been provided to demonstrate reproducible halving of the tablets.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

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.

4.3 Contra-indications

Do not use in animals with renal insufficiency, diabetes mellitus or corneal ulceration.
Do not use in animals receiving vaccines containing live organisms.
Do not use in pregnant animals.

4.4 Special warnings for each target species

There are no special warnings required for either target species.

4.5 Special precautions for use

i. Special precautions for use in animals

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 The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

iii. Other precautions

No special precautions required.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Corticosteroids are not recommended for use in pregnant animals. Studies in laboratory animals have shown that administration in 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 contra-indicated.

4.8 Interaction with other medicinal products and other forms of interaction

There are no known interactions of significance in veterinary medicine.

4.9 Amounts to be administered and administration route

For oral administration.

Dogs and cats: 0.1 - 2.0 mg per kg bodyweight per day.

A single administration may be sufficient for certain conditions such as anaphylaxis, but for more general treatment, treatment for one to 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. To minimise the risk of adrenal insufficiency, alternate day treatment may be implemented, using dose levels that adequately control the

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

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.

The tablets are divisible.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Signs of overdosage should be treated symptomatically.

4.11 Withdrawal periods

Not applicable. Prednidale 5 is not indicated for use in food-producing animals.

5. PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: Corticosteroid for systemic use
ATC Vet Code: QH02AB06

5.1 Pharmacodynamic properties

Prednisolone is a synthetic glucocorticoid with anti-inflammatory and immunosuppressant properties. It possesses only slight mineralocorticoid activity. Prednisolone is used to suppress the clinical manifestations of a wide range of disorders.

5.2 Pharmacokinetic properties

Prednisolone is readily absorbed from the gastro-intestinal tract. Peak plasma concentrations are reached one to two hours after administration, with a plasma half-life of between two and three hours. It is extensively bound to plasma proteins. It is excreted in the urine as free and conjugated metabolites and parent compound. It has a biological half-life of several hours, making it suitable for alternate-day therapy.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate, maize starch, pre-gelatinised maize starch, stearic acid, purified talc, magnesium stearate.

6.2 Incompatibilities

There are no known incompatibilities.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in tightly closed original container. Store in a dry place.

6.5 Nature and contents of immediate packaging

White polypropylene container with a white polyethylene tamper evident lid, containing 250 tablets.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 50406/5030

9. DATE OF FIRST AUTHORISATION

14 August 1998

10. DATE OF REVISION OF THE TEXT

April 2025

Gavin Hall
Approved: 08 April 2025