

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednidale 25 mg tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Prednisolone 25 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Maize starch
Pre-gelatinised maize starch
Stearic acid
Purified talc
Magnesium stearate

White, 11 mm circular tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency.

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

Personal protective equipment consisting of gloves should be worn when handling the product. Wash hands immediately after administration.
In the case of accidental ingestion, particularly by a child, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog:

Rare (1 to 10 animals / 10 000 animals treated):	Polyuria ^a Polydipsia ^a Eosinopenia, neutrophilia, lymphopenia
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Adrenal gland disorder ^b Cortisol suppression ^c , hyperalbuminaemia, elevated serum alkaline phosphatase (SAP), elevated liver enzymes, decreased aspartate transaminase, decreased lactate dehydrogenase, hypokalaemia ^d , low thyroxine (T4) Weight gain, polyphagia ^a , delayed healing (wound), weakend resistance to, or exacerbation of existing infections ^e , depression Cutaneous calcinosis, skin thinning Gastrointestinal ulceration ^f , pancreatitis Diabetes Mellitus Excitation

Undetermined frequency (cannot be estimated from the available data)	Elevated triglyceride ^g , low tri-iodothyronine (T3), elevated parathyroid (PTH) concentration Inhibition of longitudinal growth of bones Sodium and water retention ^d
--	--

^a May be caused by systemically administered corticosteroids, particularly during the early stages of therapy.

^b Following cessation of treatment, signs of adrenal insufficiency can arise, and this may render the animal unable to deal adequately with stressful situations.

^c Significant dose related suppression noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitary-adrenal-axis.

^d After long term use.

^e The immunosuppressant actions may weaken resistance to, or exacerbate existing infections.

^f May be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs.

^g The significant increase can be a part of possible iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness, wastage and osteoporosis may result.

Anti-inflammatory corticosteroids, such as prednisolone, are known to exert a wide range of side effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The use is not recommended during pregnancy.

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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Dose: 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, administration 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 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 m² and 60 mg per m² have been found to be useful. The potential risks associated with these high dose levels should be assessed before commencing treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Signs of overdosage should be treated symptomatically.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QH02AB06

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 48 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Polypropylene containers with low density polyethylene push-fit tamper evident closures containing 100 tablets.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 50406/5029

8. DATE OF FIRST AUTHORISATION

19 November 2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 09 July 2026