SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicortone 5 mg tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Prednisolone 5 mg

Excipient(s):

Qualitative composition of excipients and other constituents
Yeast (dried)
Chicken flavour
Lactose monohydrate
Cellulose, powdered
Sodium starch glycolate (Type A)
Magnesium stearate

Light brown with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

For the symptomatic treatment or as adjunct treatment of inflammatory and immune-mediated diseases in dogs and cats.

3.3 Contraindications

Do not use in animals suffering from viral or mycotic infections that are not controlled with an appropriate treatment.

Do not use in animals suffering from diabetes mellitus or hyperadrenocorticism.
Do not use in animals with osteoporosis.
Do not use in animals suffering from cardiac or renal dysfunction.
Do not use in animals suffering from corneal ulcers.
Do not use in animals with gastro-intestinal ulceration.
Do not use in animals with burns.
Do not use concomitantly with attenuated alive vaccine.
Do not use in the case of glaucoma.
Do not use during pregnancy (see section 3.7).
Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
See also section 3.8.

3.4 Special warnings

Corticoid administration is to induce an improvement in clinical signs rather than a cure. The treatment should be combined with treatment of the underlying disease and/or environmental control.

3.5 Special precautions for use

Special precautions for safe use in the target species:
In cases where a bacterial infection is present the veterinary medicinal product should be used in association with suitable antibacterial therapy.
Because of the pharmacological properties of prednisolone, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.
Corticoids such as prednisolone, exacerbate proteinaceous catabolism.
Consequently, the veterinary medicinal product should be carefully administered in old or malnourished 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 (see section 3.9).
Corticoids such as prednisolone should be used with caution in patients with hypertension, epilepsy, previous steroid myopathy, in immunocompromised animals and in young animals as corticosteroids may induce a delayed growth.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Prednisolone or other corticosteroids may cause hypersensitivity (allergic reactions).
People with known hypersensitivity to prednisolone or other corticosteroids, or any of the excipients, should avoid contact with the veterinary medicinal product.
To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.
In case of accidental ingestion, especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

Corticosteroids can cause foetal malformations; therefore, it is recommended that pregnant women avoid contact with the veterinary medicinal product.
Immediately wash hands thoroughly after handling the tablets.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very common (>1 animal / 10 animals treated):	Cortisol suppression[1], elevated triglyceride[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Excitation Pancreatitis Cushings disease[3], Diabetes mellitus Hepatomegaly Elevated serum alkaline phosphatase (ALP)[4], elevated liver enzymes, eosinopenia, neutrophilia[5], lymphopenia, hypokalaemia[6], low thyroxine (T4) Muscle weakness, muscle wasting Polyuria[7] Skin thinning, cutaneous calcinosis Polyphagia[7], polydipsia[7]
Undetermined frequency (cannot be estimated from the available data)	Gastrointestinal ulceration[8] Decreased aspartate transaminase (AST), decreased lactate dehydrogenase (LDH), hyperalbuminaemia, low tri-iodothyronine (T3), elevated parathyroid (PTH) concentration Inhibition of longitudinal growth of bones, osteoporosis Delayed healing[9], sodium and water retention[6], alteration of fat, increased weight Immunosuppression[10], weakened resistance to or exacerbation of existing infections[10] Adrenal insufficiency[11], adrenocortical atrophy[11]

[1] dose related, as a result of effective doses suppressing the hypothalamic-pituitary-adrenal axis.
[2] as part of possible iatrogenic hyperadrenocorticism (Cushings disease).
[3] iatrogenic, involving significant alteration of fat, carbohydrate, protein and mineral metabolism.
[4] could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
[5] increase of segmented neutrophils.

[6] in long-term use.
[7] after systemic administration and particularly during early stages of therapy.
[8] may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[9] wound.
[10] in the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
[11] can arise following cessation of treatment and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimizing problems of adrenal insufficiency following the withdrawal of treatment.

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. See also section 3.7.

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:
Do not use 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. See section 3.3.
Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals.
Use during lactation only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Phenytoin, barbiturates, ephedrine and rifampicin, may accelerate the metabolic clearance of corticosteroids resulting in decreased blood levels and reduced physiological effect.
The concomitant use of this veterinary medicinal product with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration. Because corticosteroids can reduce the immunoresponse to vaccination, prednisolone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of prednisolone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if prednisolone is administered together with potassium depleting diuretics.

3.9 Administration routes and dosage

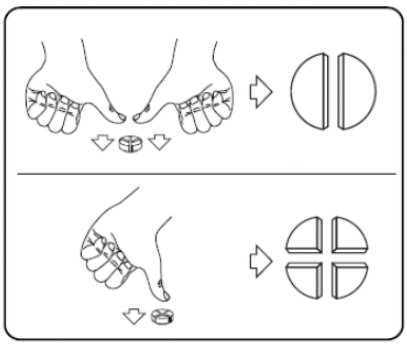
Oral use.
The dose and total duration of treatment is determined by the veterinarian per individual case depending on the severity of symptoms. The lowest effective dose must be used.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Starting dose: 0.5 – 4 mg per kg bodyweight per day.
For longer term treatment: when after a period of daily dosing the desired effect has been achieved, the dose should be reduced until the lowest effective dose is reached. The reduction of the dose should be made by alternate day therapy and /or by halving the dose with intervals of 5-7 days until the lowest effective dose is reached.

Dogs should be treated in the morning and cats in the evening on account of differences in day rhythm.

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halves: press down with your thumbs on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

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

An overdose does not cause other adverse effects than those stated in section 3.6. An antidote is not known. 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 semi-synthetic corticosteroid derived from the natural hydrocortisone (cortisol). However, the effect on the mineral and glucose metabolism is less (about half) than that of cortisol. This minimizes the unfavorable fluid retention and hypertension.
The effect of prednisolone is anti-inflammatory. When an inflammatory reaction is useful (for example to prevent further invasion of microorganisms) suppression of this defense mechanism is counterproductive. However, when the inflammatory response is excessive and/or harmful (e.g. a response to an autoimmune or allergic process), the defensive inflammatory response worsens the situation and repression by corticosteroids may be of great therapeutic importance.
-By a protein catabolic effect the formation of granulation tissue is inhibited.
-Inhibition of the inflammation is also achieved by the stabilizing effect of prednisolone on the lysosomal membranes.
-Corticosteroids reduce the development of inflammatory exudate and local oedema by stimulating vasoconstriction and by decreasing the capillary permeability.
-Anti-allergic effect and immunosuppression: these effects are partly related to the anti-inflammatory activity and are mainly directed against cellular (T–lymphocytes) immunoreactivity.
Because orally administered corticosteroids develop their therapeutic effect only after several hours, they are less suitable for the treatment of (acute) anaphylactic reactions such as septic shock.

4.3 Pharmacokinetics

Following oral administration prednisolone is well absorbed from the gastrointestinal tract and distributes in all tissues, in the body fluids and even in the cerebrospinal fluid. Prednisolone is extensively bound to plasma proteins. It is metabolized in the liver and excretion takes place mainly via the kidneys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life of the divided tablets: 4 days.

5.3 Special precautions for storage

Any unused tablet portion should be returned to the open blister space and inserted back into the carton.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

Aluminium – PVC/PE/PVDC blister.
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 25 or 50 blisters of 10 tablets.
Not all pack sizes may be marketed.

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 50406/4014

8. DATE OF FIRST AUTHORISATION

09 October 2015

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

February 2025

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: 23 July 2025