SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednizol 5 mg Tablets for Dogs and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains
Active substance:
Prednisolone 5 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
Flat faced, white circular with bevelled edges. One face embossed with letter P and reverse face with embossed with letters PL/5.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

For the symptomatic treatment of inflammatory or allergic conditions in dogs and cats.

4.3 Contraindications

Do not use in animals with:
- Viral, mycotic or parasitic infections that are not controlled with an appropriate treatment
- Diabetes mellitus
- Hyperadrenocorticism
- Osteoporosis
- Heart failure
- Severe renal insufficiency
- Corneal ulceration
- Gastro-intestinal ulceration
- Glaucoma

Do not use concomitantly with attenuated live vaccines.
Do not use in known cases of hypersensitivity to the active substance, to other corticosteroids, or to any of the excipients.
See also sections 4.7 and 4.8.

4.4 Special warnings for each target species

Glucocorticoids can produce symptomatic improvements without treating the underlying disease. Where appropriate, use of the product should be combined with treatment of the underlying disease and/or management of the affected animal's environment.

4.5 Special precautions for use

Special precautions for use in animals
In cases where a bacterial infection is present the product should be used in association with suitable antibacterial therapy.
Corticoids such as prednisolone should be used with caution in patients with hypertension, epilepsy, burns, previous steroid myopathy, in immunocompromised animals and in young animals as corticosteroids may induce a delayed growth.
Corticoids such as prednisolone, exacerbate proteinaceous catabolism. Consequently, the product should be carefully administered in old or malnourished animals.
Special monitoring is required in animals presenting with renal insufficiency. Use only after careful benefit-risk assessment by the responsible veterinarian.
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. In order to minimise the chance of adrenal insufficiency, the lowest effective dose should be used and at the end of treatment the dose used should be gradually reduced. Treatment should not be suddenly withdrawn. This is especially important following medium or long term treatment. Some cases may require continuing therapy, and in this situation the minimum effective maintenance dose should be established. It is generally considered that problems associated with the induction of adrenal insufficiency are minimised by dosing once every alternate morning for dogs and every alternate evening for cats.
See also section 4.8.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Pharmacological effects of prednisolone cannot be excluded following accidental ingestion of the product. The product is supplied in a container with a child-resistant closure, and in blisters. The cap of the container must be securely engaged after use. **If smaller quantities are dispensed from the pack, they must be supplied in a container with a child-resistant closure**. If appropriate containers are not available, the product must be supplied in the original container. Store the product safely, out of the sight and reach of children.
In case of accidental ingestion seek medical attention and show product label and/or package leaflet to the doctor.
Immediately wash hands thoroughly after handling the tablets.
People with known hypersensitivity to prednisolone or other corticosteroids should avoid contact with the veterinary medicinal product.
Corticosteroids can cause foetal malformations; therefore, it is recommended that pregnant women avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

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.
The significant dose related cortisol suppression noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitary-adrenal-axis. Following cessation of treatment, signs of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.
The significant increase in triglycerides noticed 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.
Cortisol suppression and an increase in plasma triglycerides is a very common side-effect of medication with corticoids (more than 1 in 10 animals).
Changes in biochemical, haematological and liver parameters probably associated with the use of prednisolone were significant effects noticed on alkaline phosphatase (increase), lactate dehydrogenase (decrease), albumin (increase), eosinophils, lymphocytes (decrease), segmented neutrophils (increase), alkaline phosphatase (increase) and serum hepatic enzymes (increase). A decrease in aspartate transaminase is also noticed.
Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).
Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
Other adverse reactions that may occur are: inhibition of longitudinal growth of bones; skin atrophy; diabetes mellitus; behavioural disorders (excitation and depression), pancreatitis, decrease in thyroid hormone synthesis; increase in parathyroid hormone synthesis. See also section 4.7.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Prednisolone is not recommended for use in pregnant animals. Administration of corticosteroids in early pregnancy is known to cause foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.
Prednisolone is likely to be present in milk in small quantities and may result in growth impairment in suckling young animals.
Consequently, the product should be used only according to the benefit/risk assessment of the responsible veterinary surgeon in lactating animals.

4.8 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.
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.
Precautions need to be taken when combining use with insulin.
Because corticosteroids can reduce the immune response to vaccination, a two week interval in treatment with the veterinary medicinal product should be observed before and after vaccination.

4.9 Amounts to be administered and administration route

For oral administration 0.1 - 2.0 mg per kg bodyweight per day. 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.
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. The tablets are not intended to be divided. For animals requiring a dose below 5 mg an alternative or lower strength product should be used.
Dogs should be treated in the morning and cats in the evening on account of differences in day rhythm.

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

An overdose will not cause other effects than those stated in section 4.6. There is no specific antidote. Signs of overdosage should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use, plain, glucocorticoids, prednisolone.
ATC vet code: QH02AB06

5.1 Pharmacodynamic properties

Prednisolone is a synthetic corticosteroid anti-inflammatory drug belonging to the glucocorticoid family. It has relatively slight mineralocorticoid effects.
The action of glucocorticoids in suppressing inflammation may be therapeutic in a variety of conditions. The anti-inflammatory potency differs between glucocorticoids, that of prednisolone being about four times greater than hydrocortisone but about five

times less than betamethasone. Anti-inflammatory actions are known to be the result of a wide range of effects mediated via the glucocorticoid receptor (GR). Most of the anti-inflammatory and immunosuppressive actions result from GR-mediated effects altering transcription (both up and down) of numerous genes in leukocytes. In particular, glucocorticoids repress transcription of many genes encoding pro-inflammatory cytokines and chemokines, cell adhesion molecules and key enzymes involved in the initiation and/or maintenance of the host inflammatory response.

5.2 Pharmacokinetic particulars

Prednisolone is readily absorbed from the gastro-intestinal tract and peak plasma levels are reached within 1 to 2 hours. It spreads throughout all tissues and body fluids, it crosses the placental barrier, and is excreted in small amounts in milk. Prednisolone is extensively bound to plasma proteins.
The half life varies between 2 to 4 hours and the parent plus metabolites are excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Pregelatinised Starch
Stearic Acid
Talc
Magnesium Stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

White high-density polyethylene container containing 250 tablets, sealed with a white, child-resistant, polypropylene closure.

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 15, 25 or 50 PVC Aluminium/PVC foil blisters of 10 tablets each corresponding to 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 150, 250 or 500 tablets per box.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Millpledge Ltd
Whinleys Estate
Clarborough
Retford
Nottinghamshire
DN22 9NA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

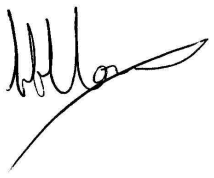
Vm 04409/5000

9. DATE OF FIRST AUTHORISATION

10 October 2019

10. DATE OF REVISION OF THE TEXT

September 2023



Approved 31 January 2024