SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicare 5 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Prednisolone 5mg

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

3. PHARMACEUTICAL FORM

Tablets
A white, biconvex tablet

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and Cats

4.2 Indications for use, specifying the target species

As an anti-inflammatory and anti-allergic agent for use 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 during pregnancy (see section 4.7).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
See also section 4.8.

4.4 Special warnings for each target species

Dosing should coincide with the endogenous cortisol peak (i.e., in the morning with regard to dogs and in the evening with regard to cats).

4.5 Special precautions for use

Special precautions for use in animals

Caution is necessary when prescribing corticosteroids in animals with the following conditions: epilepsy; hypertension; or previous steroid myopathy.

Anti-inflammatory steroids, 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 and when esters possessing a long duration of action are administered. Dosage in medium to long term should therefore generally be kept to the minimum necessary to control symptoms.

Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g., dosing on alternate days, dosing to coincide with the endogenous cortisol peak (i.e., in the morning with regard to dogs and in the evening with regard to cats) and a gradual reduction in dosage.

The immunosuppressant actions of corticosteroids may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, anti-bacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

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

Impermeable gloves should be worn when handling the veterinary medicinal product.
Wash hands thoroughly with soap and water after handling this product.
In case of accidental ingestion, drink plenty of water and seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to prednisolone should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Anti-inflammatory steroids are known to exert a wide range of side effects. Very commonly, Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g., redistribution of body fat, muscle weakness and osteoporosis may occur... Based on post marketing experience and complementary data, lethargy, diarrhoea and emesis have been observed very rarely.

During therapy, very commonly, effective doses suppress the Hypothalamic-Pituitary-Adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations.

Systemically acting corticosteroids rarely can 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).

Corticosteroids rarely can delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.

Gastrointestinal ulceration has been reported very rarely in animals treated with corticosteroids and usually with the concurrent use of non-steroidal anti-inflammatory drugs (see section 4.8).

Steroids very rarely may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

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

Corticosteroids are not recommended for use during pregnancy (see section 4.3). Administration in early pregnancy is known to have caused 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

The use of corticosteroids may render concurrent vaccinations inoperative. Corticosteroid treated animals may succumb to infection if concurrently vaccinated with live vaccines.

Gastro-intestinal tract ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid treated animals with spinal cord trauma. Serum levels of concurrently administered salicylates may increase considerably on withdrawal of corticosteroid therapy, with the potential for toxic effects and/or increased gastro-intestinal tract ulceration.

Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

The effectiveness of anticoagulants may be modified by concurrent corticosteroid therapy.

The actions of hypoglycaemic agents will be antagonised by the hyperglycaemic effects of corticosteroids.

Hypokalaemia may occur when amphotericin and corticosteroids are used concurrently.

The simultaneous use of corticosteroids and methotrexate may increase methotrexate toxicity.

The therapeutic effects of some barbiturates, phenytoin, and rifampicin may be reduced by the concurrent use of corticosteroids.

4.9 Amounts to be administered and administration route

For oral administration.

Single dose treatment may be appropriate for some specific conditions (anaphylaxis, etc), but for more general treatment, treatment may be given for one to three weeks at doses between:

DOGS:	0.1-2.0	mg/kg/day
CATS:	0.1-2.0	mg/kg/day

The lowest effective dose must be used. Treatment should not be withdrawn suddenly. Problems of adrenal insufficiency should be minimised by dosing on alternate days, dosing to coincide with the endogenous cortisol peak (i.e. in the morning with regard to dogs and in the evening with regard to cats) and a gradual reduction in dosage.

For the treatment of cats and dogs with tumours responsive to corticosteroid therapy, the balance between the risks of therapy and the benefits of treatment may justify larger doses. In such cases, doses between 20 mg/m² every other day and 60 mg/m²/day have been found to be useful. (Dose is related to the animal's estimated body surface area, in square metres.)

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

Overdose may result in disturbance of fat, carbohydrate, protein and mineral metabolism, i.e. Cushingoid signs. Treatment should be symptomatic and conservative.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Glucocorticoids.
ATC vet code: QH02AB06.

5.1 Pharmacodynamic properties

Prednisolone is a corticosteroid of the glucocorticoid class. It has anti-inflammatory activity, and has effects on tissue repair, the heart, kidneys, and central nervous system. The other principal pharmacological actions are on gluconeogenesis, glycogen deposition, and protein, lipid, and calcium metabolism, and on inhibition of corticotrophin secretion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Dextrin
Stearic Acid

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

500 or 1000 tablets in a grey or white polypropylene tub, with a white low density polyethylene lid (snap-secure).
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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER

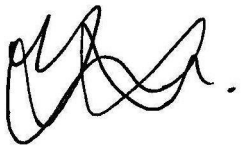
Vm 32742/4035

9. DATE OF FIRST AUTHORISATION

22 December 1997

10. DATE OF REVISION OF THE TEXT

August 2022



Approved: 11 August 2022