

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicare 5 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Prednisolone 5 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose Monohydrate
Maize Starch
Dextrin
Stearic Acid

A white, biconvex tablet.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

As an anti-inflammatory and anti-allergic agent for use in dogs and cats.

3.3 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 3.7).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

See also section 3.8.

3.4 Special warnings

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).

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product. Wash hands thoroughly with soap and water after handling this veterinary medicinal product.

In case of accidental ingestion, drink plenty of water, 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very common (>1 animal / 10 animals treated):	Cushings disease ¹ Elevated triglyceride ² Muscle weakness ² Osteoporosis ² Cortisol suppression ³
Rare (1 to 10 animals / 10,000 animals treated):	Polyuria ⁴ , polydipsia ⁴ , polyphagia ⁴ Delayed wound healing Immunosuppression, weakened resistance to or exacerbation of existing infections
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lethargy ⁵ Diarrhoea ⁵ , Emesis ⁵ , Gastrointestinal ulceration ⁶ Hepatomegaly, Elevated serum alkaline phosphatase (ALP)
Undetermined frequency (cannot be estimated from the available data)	Sodium and water retention ⁷ , hypokalaemia ⁷ Cutaneous calcinosis

¹ iatrogenic, involving significant alteration of fat, carbohydrate, protein and mineral metabolism.

² as part of possible iatrogenic hyperadrenocorticism (Cushings disease).

³ as a result of effective doses suppressing the Hypothalamic-Pituitary-Adrenal axis.

⁴ particularly during the early stages of therapy.

⁵ based on post marketing experience and complementary data.

⁶ in animals treated with corticosteroids and usually with the concurrent use of non-steroidal anti-inflammatory drugs

⁷ in long term use.

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 (see section 3.3).

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. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 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.

Gastrointestinal 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 gastrointestinal 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.

3.9 Administration routes and dosage

Oral use.

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.)

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

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

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 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.

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.

5.3 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.

5.4 Nature and composition of immediate packaging

500 or 1000 tablets in a white polypropylene HDPE tub, with a white low density polyethylene lid (snap-secure).

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

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER

Vm 32742/4035

8. DATE OF FIRST AUTHORISATION

22 December 1997

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

September 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: 30 September 2026