ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

POLYPROPYLENE TUBS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicare 5 mg Tablets

Prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains as active ingredient: Prednisolone 5mg.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

500 tablets

1000 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration. Dogs/cats 0.1 - 2.0 mg/kg/day (see package leaflet attached)

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a tightly closed original container. Do not store above 25˚C. Store in a dry place and protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary medicinal prescription.
UK authorised veterinary medicinal product.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4035

17. MANUFACTURER'S BATCH NUMBER

B. PACKAGE LEAFLET

PACKAGE LEAFLET (Concertina Label):

Prednicare 5 mg Tablets

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium

Manufacturer responsible for batch release:

Lelypharma B.V., Zuiveringsweg 42, 8243 PZ, Lelystad, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicare 5 mg Tablets

Prednisolone

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Presentation: White biconvex tablets each containing 5 mg Prednisolone.

4. INDICATION(S)

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

5. 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.

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

See also SPECIAL WARNINGS.

6. ADVERSE REACTIONS

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 SPECIAL WARNINGS).

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

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and administration: 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 of doses between:

Dogs / Cats: 0.1-2.0 mg/kg/day

For the treatment of cats and dogs with tumours responsive to corticosteroid therapy, the balance between the risk of therapy and the benefits of treatment may justify larger doses. In such cases, doses between 20mg/m^2 every other day and 60 mg/m^2/day have been found to be useful (Dose is related to animal's estimated body surface area, in square metres).

9. ADVICE ON CORRECT ADMINISTRATION

The lowest effective dose must be used.

Treatment should not be withdrawn suddenly. Problems of adrenal insufficiency following the withdrawal of treatment should be minimised by dosing on alternate days, dosing to coincide with 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.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store in a tightly closed original container. Protect from light. Store below 25°C in a dry place.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

User Warning:

Impermeable gloves should be worn when handling the veterinary medicinal product. In case of accidental ingestion drink plenty of water and seek medical advice and

show the package leaflet or the label to the physician. Wash hands thoroughly with soap and water after handling this product.

People with known hypersensitivity to prednisolone should avoid contact with the veterinary medicinal product.

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 be given to the need to minimise the risk of adrenal insufficiency following treatment withdrawal.

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.

Pregnancy and lactation:

Corticosteroids are not recommended for use during pregnancy (see CONTRAINDICATIONS). 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.

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.

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.

Overdose

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

For Animal treatment only. Not intended for use in animals intended for human consumption. To be supplied only on veterinary prescription.

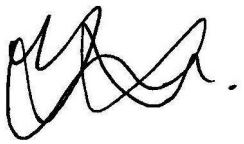
Further information: Nil

Legal category POM-V

Vm 32742/4035

Package quantities: Containers of 500 or 1000 tablets

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder



Approved: 11 August 2022