ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednizol 5 mg tablets for dogs and cats
Prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains Prednisolone 5 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 150, 250 or 500 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
The cap of the tub 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.
Wash hands thoroughly after handling the product.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

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 prescription.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04409/5000

17. MANUFACTURER'S BATCH NUMBER

Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{CONCERTINA FRONT FACE OF THE CONTAINER LABEL, WHICH IS ALSO DUPLICATED AND ATTACHED TO THE CONTAINER }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednizol 5 mg tablets for dogs and cats
Prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains Prednisolone 5 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

250 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
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.
Wash hands thoroughly after handling the product.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

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 prescription.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04409/5000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednizol 5 mg tablets for dogs and cats
Prednisolone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Millpledge

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch><Lot> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Prednizol 5 mg tablets for dogs and cats

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

Marketing authorisation holder:
Millpledge Ltd
Whinleys Estate
Clarborough
Retford
Nottinghamshire
DN22 9NA
United Kingdom

Manufacturer responsible for batch release:
Millpledge Limited
Unit 6 Heapham Road Industrial Estate
Gainsborough
Lincs
DN21 1RZ
United Kingdom

Or

Millpledge Europe BVBA
38 Verrekijker
8750 Wingene
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednizol 5 mg tablets for dogs and cats
Prednisolone

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

Each tablet contains Prednisolone 5 mg.
White circular flat faced tablet with bevelled edges. One face embossed with letter P and reverse face with embossed with letters PL/5.

4. INDICATION(S)

For the symptomatic treatment of inflammatory or allergic conditions 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 in known cases of hypersensitivity to the active substance, to other corticosteroids, or to any of the excipients.
Also see 'Special Warnings' section.

6. ADVERSE REACTIONS

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 on 'Pregnancy and lactation'.

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

For oral administration 0.1 - 2.0 mg per kg bodyweight per day.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the container.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

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 on 'Interactions'.

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.

Pregnancy and lactation:
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.
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.

Overdose (symptoms, emergency procedures, antidotes):
An overdose will not cause other effects than those stated in the section 'Adverse Reactions'. There is no specific antidote. Signs of overdosage should be treated symptomatically.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

Pack sizes
Container containing 250 tablets.
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.

For animal treatment only. To be supplied only on veterinary prescription.
Keep out of the sight and reach of children.

Approved 31 January 2024