ANNEX III

LABELLNG AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicortone 5 mg tablets for dogs and cats
prednisolone

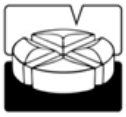
2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains
Active substance:

Prednisolone 5 mg

3. PHARMACEUTICAL FORM

Tablet.



Divisible tablet

4. PACKAGE SIZE

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP .....
Shelf life of the divided tablets: 4 days

11. SPECIAL STORAGE CONDITIONS

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 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

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4014

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Alu/PVC/PE/PvDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicortone 5 mg tablets
prednisolone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot.

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Prednicortone 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:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for the batch release:
LelyPharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

Genera Inc.
Svetonedeljska cesta 2
10436 Rakov Potok
Croatia

Only the site testing and releasing the batches will be mentioned on the printed leaflet.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednicortone 5 mg tablets for dogs and cats
prednisolone

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains
Active substance:

Prednisolone 5 mg

Light brown with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

4. INDICATION(S)

For the symptomatic treatment or as adjunct treatment of inflammatory and immune-mediated diseases in dogs and cats.

5. CONTRAINDICATIONS

Do not use in animals suffering from viral or mycotic infections that are not controlled with an appropriate treatment.
Do not use in animals suffering from diabetes mellitus or hyperadrenocorticism.
Do not use in animals with osteoporosis.
Do not use in animals suffering from cardiac or renal dysfunction.
Do not use in animals suffering from corneal ulcers.
Do not use in animals with gastrointestinal ulceration.
Do not use in animals with burns.
Do not use concomitantly with attenuated alive vaccine.
Do not use in the case of glaucoma.
Do not use during pregnancy (see also section: Special warnings; Use during pregnancy and lactation)
Do not use in known cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
See also section: Interactions with other medicinal products and other forms of interaction.

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. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.
The significant dose related cortisol suppression noticed during therapy is a result of effective doses suppressing the hypothalamo-pituitreal adrenal axis. Following cessation of treatment, signs of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment.
The significant increase in triglycerids noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushings disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage and osteoporosis may result. Cortisol suppression and an increase in plasma tryglicerids is a very common side-effect of medication with corticoids (more than 1 in 10 animals).
The increase of alkaline phosphatase by glucocorticoids could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
Other changes in blood biochemical and haematological parameters probably associated with the use of prednisolone were significant effects noticed on lactate dehydrogenase (decrease) and albumin (increase) and on eosinophils, lymphocytes (decrease) and segmented neutrophils (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. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.

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; euphoria, pancreatitis, decrease in thyroid hormone synthesis; increase in parathyroid hormone synthesis.
See also the section on Special Warnings: Use during pregnancy and lactation.

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

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.

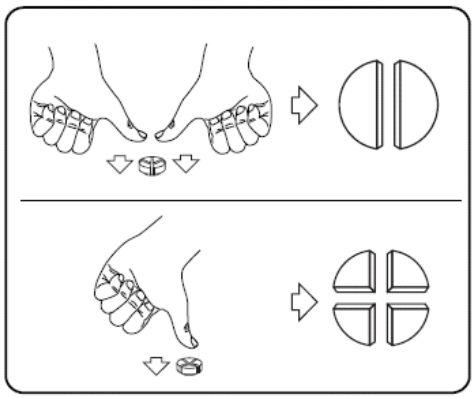
8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Oral use.
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.

Starting dose: 0.5 - 4 mg per kg bodyweight per day.
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.

9. ADVICE ON CORRECT ADMINISTRATION

Dogs should be treated in the morning and cats in the evening on account of differences in day rhythm.
Tablets can be divided into equal 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halves: press down with your thumbs on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf life of the divided tablets: 4 days.
Any unused tablet portion should be returned to the open blister space and inserted back into the carton.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species
Corticoid administration is to induce an improvement in clinical signs rather than a cure. The treatment should be combined with treatment of the underlying disease and/or environmental control.

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.
Because of the pharmacological properties of prednisolone, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.
Corticoids such as prednisolone, exacerbate proteinaceous catabolism. Consequently, the product should be carefully administered in old or malnourished animals.
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. Adrenal insufficiency may be minimised by institution of alternate-day therapy if practical. The dosage should be reduced and

withdrawn gradually to avoid precipitation of adrenal insufficiency (see section on: Amounts to be administered and administration route).
Corticoids such as prednisolone should be used with caution in patients with hypertension, epilepsy, previous steroid myopathy, in immunocompromised animals and in young animals as corticosteroids may induce a delayed growth.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Prednisolone or other corticosteroids may cause hypersensitivity (allergic reactions).

- People with known hypersensitivity to prednisolone or other corticosteroids, or any of the excipients, should avoid contact with the veterinary medicinal product.
- To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.
- In case of accidental ingestion, especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
- Corticosteroids can cause foetal malformations; therefore it is recommended that pregnant women avoid contact with the veterinary medicinal product.
- Immediately wash hands thoroughly after handling the tablets.

Pregnancy and lactation
Do not use in pregnant animals. Studies in laboratory animals have shown that administration during early pregnancy may cause foetal abnormalities. Administration during the later stages of pregnancy may cause abortion or early parturition. See also the section on contraindications.
Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals.
Use during lactation only according to the benefit /risk assessment by the responsible veterinarian.

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. Because corticosteroids can reduce the immunoresponse to vaccination, prednisolone should not be used in combination with vaccines or within two weeks after vaccination.
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.

Overdose (symptoms, emergency procedures, antidotes)
An overdose does not cause other adverse effects than those stated in the section on adverse reactions. An antidote is not known.

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

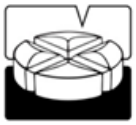
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 25 or 50 blisters of 10 tablets
Not all pack sizes may be marketed.



Divisible tablet

Approved 07 April 2022