ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 20 mg tablets for dogs

Prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Prednisolone 20 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

20 tablets
100 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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 {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C
Any unused tablet portion should be returned to the blister and be used for the next administration.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/3044

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 20 mg tablets for dogs
Prednisolone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Dermipred 5 mg tablets for dogs

Dermipred 10 mg tablets for dogs

Dermipred 20 mg tablets for dogs

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la communication
Zone Autoroutière
53950 LOUVERNE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 5 mg tablets for dogs

Dermipred 10 mg tablets for dogs

Dermipred 20 mg tablets for dogs

Prednisolone

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

Dermipred 5 mg
Each tablet contains:
Active substance
Prednisolone 5.0 mg
Oblong shaped beige to light brown tablet, with one score line on one side.
The tablets can be divided into two equal parts.

Dermipred 10 mg
Each tablet contains:
Active substance
Prednisolone 10.0 mg
Round shaped beige to light brown tablet, with double score line on one side.
The tablets can be divided into two or four equal parts.

Dermipred 20 mg
Each tablet contains:
Active substance
Prednisolone 20.0 mg
Round shaped beige to light brown tablet, with double score line on one side.
The tablets can be divided into two or four equal parts.

4. INDICATION(S)

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

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.
See also sections “Pregnancy and lactation” and “Interaction with other medicinal products and other forms of interaction”.

6. ADVERSE REACTIONS

Anti-inflammatory corticosteroids may induce severe side-effects in long term use.
Effects generally are manifested as clinical signs of hyperadrenocorticism (Cushing's disease in dogs) involving redistribution of body fat, weight gain, muscle weakness, wastage, calcinosis and osteoporosis.
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 such as increase in serum hepatic enzymes and neutrophils or decrease in lymphocytes.
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. 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.
Other adverse reactions that may occur are: inhibition of longitudinal growth of bones; skin atrophy; diabetes mellitus; behavioral disorders (excitation and depression), pancreatitis, decrease in thyroid hormone synthesis; increase in parathyroid hormone synthesis.
Following cessation of treatment, signs of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations. See also section "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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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:
- for dermatitis requiring an anti-inflammatory dose: 0.5 mg per kg bodyweight twice a day.
- for dermatitis requiring an immunosuppressive dose: 1 - 3 mg per kg bodyweight twice a 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.

For example, for a 10 kg dog requiring an anti-inflammatory dose of 0.5 mg/kg twice a day, give one-half of a 10 mg-tablet twice a day.

9. ADVICE ON CORRECT ADMINISTRATION

Spontaneous intake by the animal or place the tablet behind the lingual torus.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C
Any unused tablet portion should be returned to the blister and be used for the next administration.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton label after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Glucocorticoids 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 Pharmacologically-active dose levels may result adrenal insufficiency. This may become apparent particularly after withdrawal of corticosteroid treatment. This effect 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 "DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION").
Corticoids such as prednisolone, exacerbate proteinaceous catabolism. Consequently, the product should be carefully administered in old or malnourished animals.
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.
Treatment with the veterinary medicinal product may interfere with vaccination efficacy. (See section" Interaction with other medicinal products and other forms of interaction")
Special monitoring is required in animals presenting with renal insufficiency. Use only after careful benefit-risk assessment by the responsible veterinarian.
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
Prednisolone is not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.
Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals. In lactating animals use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
Concomitant use of medicines containing the active substances phenytoin, barbiturates, ephedrine and rifampicin may reduce the effect of the product.
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.
When vaccinating with attenuated live vaccines, a two week interval should be observed before or after treatment.

Overdose (symptoms, emergency procedures, antidotes), if necessary
An overdose will not cause other effects than those stated in section “Adverse reactions”
There is no specific antidote.

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 2022

15. OTHER INFORMATION

Dermipred 5 mg
Cardboard box with 20 tablets, 24 tablets or 120 tablets

Dermipred 10 mg

Cardboard box with 16 tablets or 96 tablets

Dermipred 20 mg
Cardboard box with 20 tablets or 100 tablets

Not all pack sizes may be marketed.

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

Approved 30 September 2022