PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 10 mg tablets for dogs
Prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Prednisolone 10 mg

3. PACKAGE SIZE

15 tablets
16 tablets
90 tablets
96 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}

9. 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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5080
Vm 14966/3079

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (BLISTERS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 10 mg tablets for dogs
Prednisolone

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains Prednisolone 10 mg.

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. 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

2. Composition

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.

3. Target species

Dogs

4. Indications for use

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. Special warnings

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 safe use in the target species
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.

Special precautions for the protection of the environment:
Not applicable

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:
An overdose will not cause other effects than those stated in section “Adverse reactions”. There is no specific antidote.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Elevated triglyceride, hypocortisolaemia[1] Hypoadrenocorticism[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperadrenocorticism **(iatrogenic)**, Cushing's disease **(iatrogenic)**, diabetes mellitus Low thyroxine (T4), elevated liver enzymes, elevated serum alkaline phosphatase (ALP), eosinopenia, lymphopenia, neutrophilia Muscle wasting Polyuria[2] Polydipsia[2], polyphagia[2] **Skin thinning** Gastrointestinal ulceration[3], pancreatitis Behavioural disorders, **excitation, depression**
Undetermined frequency (cannot be estimated from the available data)	Elevated parathyroid (PTH) concentration, decreased lactate dehydrogenase (LDH), decreased aspartate **aminotransferase** (**AST**), hyperalbuminemia, hypernatraemia[4], hypokalaemia[4] Muscle weakness, osteoporosis, inhibition of longitudinal growth of bones Increased weight, delayed healing, water retention, redistribution of body fat **Opportunistic infection[5]** Cutaneous calcinosis

[1] is a consequence of the suppression of the hypothalamic-pituitary-adrenal axis. Signs of adrenal insufficiency can arise following cessation of treatment, and this may render the animal unable to deal adequately with stressful situations
[2] particularly during the early stages of therapy
[3] may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[4] in case of long-term use.
[5] the immunosuppressant action of corticosteroids may weaken resistance to or exacerbate existing infections.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes

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 periods

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 precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Dermipred 5 mg, Vm 14966/5033, Vm 14966/3032
Cardboard box with 20 tablets, 24 tablets or 120 tablets
Dermipred 10 mg, Vm 14966/5080, UK(NI) Vm 14966/3079
Cardboard box with 16 tablets or 96 tablets
Cardboard box with 15 tablets or 90 tablets
Dermipred 20 mg, Vm 14966/5081, Vm 14966/3080
Cardboard box with 20 tablets or 100 tablets

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing Authorisation Holder:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:

Ceva Animal Health Ltd
Explorer House, Mercury Park
Wycombe Lane, Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: 00800 35 22 11 51
Email for the reporting of adverse events: pharmacovigilance@ceva.com

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

17. Other information

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

Gavin Hall

Approved: 29 April 2026