1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 10 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance
Prednisolone 10.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Yeast
Pig liver powder
Silica, colloidal anhydrous
Glycerol distearate
Cellulose, microcrystalline

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. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 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 incases of hypersensitivity to the active substance, to other corticosteroids, or to any of the excipients.
See also sections 3.7 and 3.8.

3.4 Special warnings

Glucocorticoids administration is intended 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
In cases where a bacterial infection is present the veterinary medicinal product should be used in association with suitable antibacterial therapy. Pharmacologically-active dose levels may result in 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 The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency (see section 3.9).
Corticoids such as prednisolone, exacerbate proteinaceous catabolism. Consequently, the veterinary medicinal 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 3.8).
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

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.
When vaccinating with attenuated live vaccines, a two-week interval should be observed before or

after treatment.

3.9 Administration routes and dosage

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.

Spontaneous intake by the animal or place the tablet directly in the mouth.

3.10 Symptoms of overdose (and where applicable, emergency procedures, and antidotes)

An overdose will not cause other effects than those stated in section 3.6.
There is no specific antidote.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet Code:

QH02AB06

4.2 Pharmacodynamics

Prednisolone is a synthetic corticosteroid anti-inflammatory drug belonging to the glucocorticoid family. The main effects of prednisolone are the same as those of glucocorticoids:

Anti-inflammatory action:
The anti-inflammatory properties of prednisolone are expressed at a low dose and are explained by:
- the inhibition of phospholipase A_2, which reduces the synthesis of arachidonic acid, a precursor of many proinflammatory metabolites. Arachidonic acid is released from the phospholipid component of the cell membrane by the action of phospholipase A_2. The corticosteroids indirectly inhibit this enzyme by inducing the endogenous synthesis of polypeptides, lipocortins, which have an anti-phospholipase action;
- by a membrane stabilising effect, particularly in relation to lysosomes, thus preventing enzymes from being released outside the lysosomal compartment.

Immunosuppressive action:
The immunosuppressive properties of prednisolone are expressed at a higher dose on both the macrophages (slower phagocytosis, decreased flow to inflammatory foci) and the neutrophils and lymphocytes. Administration of prednisolone reduces the production of antibodies and inhibits several complement components.

Antiallergic action:
Like all corticosteroids, prednisolone inhibits the release of histamine by mast cells. Prednisolone is active in all manifestations of allergy as a complement to the specific treatment.

4.3 Pharmacokinetics

Following oral administration, prednisolone is rapidly and almost completely absorbed in the gastrointestinal tract (80%).

It is highly (90%) and reversibly bound to plasma proteins.
It spreads throughout all tissues and body fluids, it crosses the placental barrier, and is excreted in small amounts in breast milk.

Prednisolone is excreted in urine in both unchanged form and as sulpho-and glucurono-conjugated metabolites.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25°C.
Any unused tablet portion should be returned to the blister and be used for the next administration.

5.4 Nature and composition of immediate packaging

Aluminium / Polyvinylidene chloride - Thermo elast - Polyvinyl chloride blister containing 16 tablets.
Aluminium / Polyvinyl chloride - Aluminium - Polyamide blister containing 16 tablets.

Cardboard box with 16 tablets or 96 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/029/002

8. DATE OF FIRST AUTHORISATION

11/11/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

17/10/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).