

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 5 mg tablets for dogs

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

**Active substance**

Prednisolone 5.0 mg

**Excipients:**

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

Oblong shaped beige to light brown tablet, with one score line on one side.

The tablets can be divided into two equal parts

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs

### 4.2 Indications for use, specifying the target species

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

### 4.3 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 in known cases of hypersensitivity to the active substance, to other corticosteroids, or to any of the excipients.

See also sections 4.7 and 4.8.

### 4.4 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.

## 4.5 Special precautions for use

### 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 The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency (see section 4.9).

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

Special monitoring is required in animals presenting with renal insufficiency. Use only after careful benefit-risk assessment by the responsible veterinarian.

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

### Special precautions for the person administering the veterinary medicinal product to animals:

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to prednisolone or other corticosteroids, or any of the excipients, 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.

Immediately wash hands thoroughly after handling the tablets.

## 4.6 Adverse reactions (frequency and seriousness)

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; behavioral disorders (excitation and depression), pancreatitis, decrease in thyroid hormone synthesis; increase in parathyroid hormone synthesis. See also section 4.7

#### 4.7 Use during pregnancy, lactation or lay

Corticosteroids are 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. Consequently, the product should be used only according to the benefit / risk assessment of the responsible veterinary surgeon in lactating bitches.

#### 4.8 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.

#### 4.9 Amounts to be administered and administration route

For oral 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.

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,

Number of tablets for a dose regimen of 1 mg/kg/day in two equally divided doses - equivalent to the anti-inflammatory dose of 0.5 mg/kg BID

Body weight (kg) 0.5mg/kg	Dermipred 5 mg Number of tablets (twice daily)	Dermipred 10 mg Number of tablets (twice daily)	Dermipred 20 mg Number of tablets (twice daily)
3 – 5	½	¼	
6 – 10	1	½	¼
11 – 15		¾	
16 – 20		1	½
21 – 25		1 ¼	
26 – 30			¾
31 – 40			1

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

#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

An overdose will not cause other effects than those stated in section 4.6.

There is no specific antidote.

#### 4.11 Withdrawal Period(s)

Not applicable.

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use, plain, glucocorticoids, prednisolone.

Code ATCvet : QH02AB06

#### 5.1 Pharmacodynamic properties

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<sub>2</sub>, 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<sub>2</sub>. 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.

#### 5.2 Pharmacokinetic properties

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 sulfo- and glucurono-conjugated metabolites.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Yeast  
 Pig liver powder  
 Silica, colloidal anhydrous  
 Glycerol distearate  
 Cellulose, microcrystalline

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf-life**

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

## **6.4 Special precautions for storage**

Do not store above 30 ° C

Any unused tablet portion should be returned to the blister and be used for the next administration.

## **6.5 Nature and composition of immediate packaging**

Aluminium / Polyvinylidene chloride - Thermo elast - Polyvinyl chloride blister containing 12 tablets.

Aluminium / Polyvinyl chloride - Aluminium - Polyamide blister containing 10 tablets.

Cardboard box with 24 tablets or 120 tablets (Al/PVDC - TE - PDC)

Cardboard box with 20 tablets or 120 tablets (Al/PVC – Al – OPA)

Not all pack sizes may be marketed.

## **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

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

## **7 MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10 Avenue de la Ballastiére  
33500 Libourne  
France

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10815/029/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 11<sup>th</sup> November 2016

## **10 DATE OF REVISION OF THE TEXT**