ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 5 mg tablets for dogs
Prednisolone Ceva 5 mg tablets for dogs (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance
Prednisolone 5.0 mg

Excipients:

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

Oblong shaped beige to light brown tablet, with one score line on one side.
The tablets can be divided into two 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 The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency (see section 3.9).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 12 tablets.
Aluminium / Polyvinyl chloride - Aluminium - Polyamide blister containing 10 tablets.

Cardboard box with 24 tablets or 120 tablets (Al/PVDC - TE - PVC).
Cardboard box with 20 tablets or 120 tablets (Al/PVC – Al – OPA).

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{mm/yyyy}

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Not applicable

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 20 or 24 or 120 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred 5 mg tablets
Prednisolone Ceva 5 mg tablets (FR)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Prednisolone 5 mg

3. PACKAGE SIZE

20 tablets
24 tablets
120 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°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

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

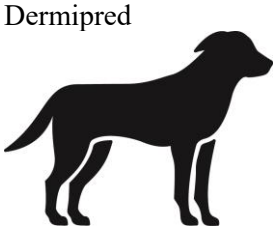
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermipred



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

5 mg of prednisolone

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Dermipred 5 mg tablets for dogs
Prednisolone Ceva 5 mg tablets for dogs (FR)

Dermipred 10 mg tablets for dogs

Dermipred 20 mg tablets for dogs (

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 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

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.

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 minimized 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 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" 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 pac
kage 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:
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.

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

7. Adverse events

Dogs :

Very common (>1 animal / 10 animals treated):
Laboratory findings : Elevated triglyceride, hypocortisolaemia (low level of cortisol in the blood) [1]. Hypoadrenocorticism[1].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hyperadrenocorticism (iatrogenic), Cushing's disease (iatrogenic), diabetes mellitus. Laboratory findings: Low thyroxine (T4), elevated liver enzymes, elevated serum alkaline phosphatase (ALP), eosinopenia, lymphopenia, neutrophilia. Clinical signs: Muscle wasting, polyuria (increased urine production)[2], polydipsia (increased thirst)[2], polyphagia (increased appetite)[2], skin thinning, gastrointestinal ulceration[3], pancreatitis, behavioural disorders, excitation, depression.
Undetermined frequency (cannot be estimated from the available data):
Laboratory findings: Elevated parathyroid (PTH) concentration, decreased lactate dehydrogenase (LDH), decreased aspartate aminotransferase (AST), hyperalbuminemia (increased level of albumin in blood), hypernatraemia (increased level of sodium in blood) [4], hypokalaemia (decreased level of potassium in blood)[4]. Clinical signs: Muscle weakness, osteoporosis, inhibition of longitudinal growth of bones, increased weight, delayed healing, water retention, redistribution of body fat, opportunistic infection[5], cutaneous calcinosis (calcium deposits into the skin).

[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.

8. Dosage for each species, routes 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 directly in the mouth.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Do not store above 25°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 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist 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

(MA)

Pack sizes:

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.

15. Date on which the package leaflet was last revised

{mm/yyyy}
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
(Name and address to be completed nationally)
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

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

17. Other information