ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hydrocortisone aceponate Ecuphar 0.584 mg/ml cutaneous spray solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains:

Active substance
Hydrocortisone aceponate 0.584 mg
Equivalent to 0.460 mg of hydrocortisone

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.
Clear colourless to slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.
For alleviation of clinical signs associated with atopic dermatitis in dogs.

4.3 Contraindications

Do not use on cutaneous ulcers.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Clinical signs of atopic dermatitis such as pruritus and skin inflammation are not specific for this disease and therefore other causes of dermatitis such as ectoparasitic infestations and infections which cause dermatological signs should be ruled out before treatment is started, and underlying causes should be investigated.

In the case of concurrent microbial disease or parasitic infestation, the dog should receive appropriate treatment for such condition.

In the absence of specific information, the use in animals suffering from Cushing's syndrome shall be based on the risk-benefit assessment.

Since glucocorticosteroids are known to slow growth, use in young animals (under 7 months of age) shall be based on the risk-benefit assessment and subject to regular clinical evaluations.

Total body surface treated should not exceed approximately 1/3 of the dog's surface corresponding for example to a treatment of two flanks from the spine to the mammary chains including the shoulders and the thighs. See also section 4.10. Otherwise, use only according to the risk-benefit assessment of the responsible veterinary surgeon and subject the dog to regular clinical evaluations as further described in section 4.9.

Care should be taken to avoid spraying into the eyes of the animal.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

The active substance is potentially pharmacologically active at high doses of exposure.
The formulation may cause eye irritation following accidental ocular contact.
The formulation is flammable.

Wash hands after use. Avoid contact with eyes.
To avoid skin contact, recently treated animals should not be handled until the application site is dry.
To avoid inhalation of the product, apply the spray in a well-ventilated area.
Do not spray on naked flame or any incandescent material.
Do not smoke while handling the veterinary medicinal product.
Replace the bottle in the outer carton and in a safe place out of the sight and the reach of children immediately after use.

In case of accidental skin contact, avoid hand-to-mouth contact and wash the exposed area immediately with water.
In case of accidental eye contact, rinse with abundant quantities of water.
If eye irritation persists, seek medical advice.
In case of accidental ingestion, especially by children, seek medical advice immediately and show the leaflet or the label to the physician.

Other precautions

The solvent in this product may stain certain materials including painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

4.6 Adverse reactions (frequency and seriousness)

Transient local reactions at the application site (erythema and/or pruritus) can occur in very rare cases.

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).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Systemic absorption of hydrocortisone aceponate being negligible, it is unlikely for teratogenic, foetotoxic, maternotoxic effects to happen at the recommended dosage in dogs. Use only accordingly to the risk-benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.
In the absence of information, it is recommended not to apply other topical preparations simultaneously on the same lesions.

4.9 Amounts to be administered and administration route

Cutaneous use.
Before administration, screw the pump spray on the bottle.
The veterinary medicinal product is then applied by activating the pump spray, from a distance of about 10 cm of the area to be treated.
The recommended dosage is 1.52 µg of hydrocortisone aceponate/cm^2 of affected skin per day. This dosage can be achieved with two pump spray activations over a surface to be treated equivalent to a square of 10 cm x 10 cm.

– For treatment of inflammatory and pruritic dermatoses, repeat the treatment daily for 7 consecutive days.
  In case of conditions requiring an extended treatment, the responsible veterinarian should subject the use of the veterinary medicinal product to the risk-benefit assessment.
  If signs fail to improve within 7 days, treatment should be re-evaluated by the veterinarian.

– For alleviation of clinical signs associated with atopic dermatitis, repeat the treatment daily for at least 14 and up to 28 consecutive days.
  An intermediary control by the veterinarian at day 14 should be made to decide if further treatment is needed. The dog should be re-evaluated regularly with regard to HPA suppression or skin atrophy, both being possibly asymptomatic.
  Any prolonged use of this product, to control atopy, should be at the benefit risk assessment of the responsible veterinary surgeon. It should take place after a re-evaluation of the diagnosis and also a consideration of the multi-modal treatment plan in the individual animal.

Presented as a volatile spray, this veterinary medicinal product does not require any massage.

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

Tolerance studies of multiple doses were assessed over a period of 14 days in healthy dogs using 3 and 5 times the recommended dosage corresponding to the two flanks, from the spine to the mammary chains including the shoulder and the thighs (1/3 of the dog's body surface area). These resulted in a reduced capacity for production of cortisol that is fully reversible within 7 to 9 weeks after the end of treatment.
In 12 dogs suffering from atopic dermatitis, after topical application once a day at the recommended therapeutic dosage for 28 to 70 (n=2) consecutive days, no noticeable effect on the systemic cortisol level was observed.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids, dermatological preparations.
ATC vet code: QD07AC16.

5.1 Pharmacodynamic properties

The veterinary medicinal product contains the active substance hydrocortisone aceponate. Hydrocortisone aceponate is a dermocorticoid with a potent intrinsic glucocorticoid activity which means a relief of both inflammation and pruritus leading to a quick improvement of skin lesions observed in case of inflammatory and pruritic dermatosis. In case of atopic dermatitis, improvement will be slower.

5.2 Pharmacokinetic particulars

Hydrocortisone aceponate belongs to the diesters class of the glucocorticosteroids. The diesters are lipophilic components ensuring an enhanced penetration into the skin associated to a low plasma availability. Hydrocortisone aceponate thus accumulates in the dog's skin allowing local efficacy at low dosage. The diesters are transformed inside the skin structures. This transformation is responsible for the potency of the therapeutic class. In laboratory animals, hydrocortisone aceponate is eliminated the same way as hydrocortisone (other name for endogenous cortisol) through urine and faeces. Topical application of diesters results in high therapeutic index: high local activity with reduced systemic secondary effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol methyl ether.

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 6 months.

6.4. Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

White polyethylene terephthalate (PET) bottle closed with a white polypropylene screw cap with bore seal and supplied with a spray pump.
Cardboard box containing 1 bottle of 76 ml.

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

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp

Belgium

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/230/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/08/2018

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

DIVASA-FARMAVIC, S.A.
Ctra. Sant Hipòlit, km 71
08503 Gurb-Vic, Barcelona
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Specific pharmacovigilance requirements:

PSUR submissions shall be synchronised and submitted at the same frequency as for the reference product.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hydrocortisone aceponate Ecuphar 0.584 mg/ml cutaneous spray solution for dogs
hydrocortisone aceponate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 0.584 mg of hydrocortisone aceponate.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

76 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Cutaneous use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Spray preferably in a well ventilated area. Flammable.
Do not spray on naked flame or any incandescent material. Do not smoke while handling the product.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/230/001

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE (PET)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hydrocortisone aceponate Ecuphar 0.584 mg/ml cutaneous spray solution for dogs
hydrocortisone aceponate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 0.584 mg of hydrocortisone aceponate.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

76 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/230/001

17. MANUFACTURER'S BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Hydrocortisone aceponate Ecuphar 0.584 mg/ml cutaneous spray solution 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:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:
DIVASA-FARMAVIC, S.A.
Ctra. Sant Hipòlit, km 71
08503 Gurb-Vic, Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hydrocortisone aceponate Ecuphar 0.584 mg/ml cutaneous spray solution for dogs
hydrocortisone aceponate

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

Hydrocortisone aceponate 0.584 mg/ml.
Clear colourless to slightly yellow solution.

4. INDICATION(S)

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.
For alleviation of clinical signs associated with atopic dermatitis in dogs.

5. CONTRAINDICATIONS

Do not use on cutaneous ulcers.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Transient local reactions at the application site (erythema and/or pruritus) can occur in very rare cases.

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.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cutaneous use.
Before administration, screw the pump spray on the bottle.
The veterinary medicinal product is then applied by activating the pump spray, from a distance of about 10 cm of the area to be treated.
The recommended dosage is 1.52 µg of hydrocortisone aceponate/cm^2 of affected skin per day. This dosage can be achieved with two pump spray activations over a surface to be treated equivalent to a square of 10 cm x 10 cm.

– For treatment of inflammatory and pruritic dermatoses, repeat the treatment daily for 7 consecutive days.
  In case of conditions requiring an extended treatment, the responsible veterinarian should subject the use of the veterinary medicinal product to the risk-benefit assessment.
  If signs fail to improve within 7 days, treatment should be re-evaluated by the veterinarian.

– For alleviation of clinical signs associated with atopic dermatitis, repeat the treatment daily for at least 14 and up to 28 consecutive days.
  An intermediary control by the veterinarian at day 14 should be made to decide if further treatment is needed. The dog should be re-evaluated regularly with regard to HPA suppression or skin atrophy, both being possibly asymptomatic.
  Any prolonged use of this product, to control atopy, should be at the benefit risk assessment of the responsible veterinary surgeon. It should take place after a re-evaluation of the diagnosis and also a consideration of the multi-modal treatment plan in the individual animal.

9. ADVICE ON CORRECT ADMINISTRATION

Spray preferably in a well ventilated area. Flammable.
Do not spray on naked flame or any incandescent material. Do not smoke while handling the product.
Presented as a volatile spray, this veterinary medicinal product does not require any massage.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 6 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Clinical signs of atopic dermatitis such as pruritus and skin inflammation are not specific for this disease and therefore other causes of dermatitis such as ectoparasitic infestations and infections which cause dermatological signs should be ruled out before treatment is started, and underlying causes should be investigated.

In the case of concurrent microbial disease or parasitic infestation, the dog should receive appropriate treatment for such condition.

In the absence of specific information, the use in animals suffering from Cushing's syndrome shall be based on the risk-benefit assessment.
Since glucocorticosteroids are known to slow growth, use in young animals (under 7 months of age) shall be based on the risk-benefit assessment and subject to regular clinical evaluations.

Total body surface treated should not exceed approximately 1/3 of the dog's surface corresponding for example to a treatment of two flanks from the spine to the mammary chains including the shoulders and the thighs. See also section 'Overdose'. Otherwise, use only according to the risk-benefit assessment of the responsible veterinary surgeon and subject the dog to regular clinical evaluations as further described in section 'Dosage for each species, route(s) and method of administration'.

Care should be taken to avoid spraying into the eyes of the animal.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The active substance is potentially pharmacologically active at high doses of exposure.
The formulation may cause eye irritation following accidental ocular contact.
The formulation is flammable.

Wash hands after use. Avoid contact with eyes.
To avoid skin contact, recently treated animals should not be handled until the application site is dry.
To avoid inhalation of the product, apply the spray in a well-ventilated area.
Do not spray on naked flame or any incandescent material.
Do not smoke while handling the veterinary medicinal product.
Replace the bottle in the outer carton and in a safe place out of the sight and the reach of children immediately after use.

In case of accidental skin contact, avoid hand-to-mouth contact and wash the exposed area immediately with water.
In case of accidental eye contact, rinse with abundant quantities of water.
If eye irritation persists, seek medical advice.
In case of accidental ingestion, especially by children, seek medical advice immediately and show the leaflet or the label to the physician.

Other precautions:

The solvent in this product may stain certain materials including painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Systemic absorption of hydrocortisone aceponate being negligible, it is unlikely for

teratogenic, foetotoxic, maternotoxic effects to happen at the recommended dosage in dogs. Use only accordingly to the risk-benefit assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

In the absence of information, it is recommended not to apply other topical preparations simultaneously on the same lesions.

Overdose (symptoms, emergency procedures, antidotes):

Tolerance studies of multiple doses were assessed over a period of 14 days in healthy dogs using 3 and 5 times the recommended dosage corresponding to the two flanks, from the spine to the mammary chains including the shoulder and the thighs (1/3 of the dog's body surface area). These resulted in a reduced capacity for production of cortisol that is fully reversible within 7 to 9 weeks after the end of treatment.
In 12 dogs suffering from atopic dermatitis, after topical application once a day at the recommended therapeutic dosage for 28 to 70 (n=2) consecutive days, no noticeable effect on the systemic cortisol level was observed.

Incompatibilities:

None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Hydrocortisone aceponate administered topically accumulates and is metabolised in skin, as suggested by radioactivity distribution studies and pharmacokinetic data. This results in minimal amounts to reach the blood stream. This particularity will increase the ratio between the desired local anti-inflammatory effect in the skin and the undesirable systemic effects.
Hydrocortisone aceponate applications on the skin lesions provide rapid reduction of the skin redness, irritation and scratching while minimising the general effects.
White polyethylene terephthalate (PET) bottle closed with a white polypropylene screw cap with bore seal and supplied with a push in pump spray.
Cardboard box containing 1 bottle of 76 ml.

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

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