ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CORTAVANCE 0.584 mg/ml cutaneous spray solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Hydrocortisone aceponate 0.584 mg/ml.

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, 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.

4.3 Contraindications

Do not use on cutaneous ulcers.

4.4 Special warnings for each target species

Total body surface treated should not exceed a surface corresponding for example to a treatment of two flanks from the spine to the mammary chains including the shoulders and the thighs. Otherwise, use only according to the risk-benefit assessment and subject the dog to regular clinical evaluations.

4.5 Special precautions for use

Special precautions for use in animals

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 animal 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.
In 12 dogs suffering from atopic dermatitis, after topical application on the skin at the recommended therapeutic dosage for 28 to 70 consecutive days, no noticeable effect on the systemic cortisol level was observed.

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

In case of accidental skin contact, it is recommended to wash thoroughly with water. Wash hands after use.
Avoid contact with eyes. In case of accidental eye contact, rinse with abundant quantities of water. In case of eye irritation, seek medical advice.
In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.

Spray preferably in a well ventilated area.
Flammable.
Do not spray on naked flame or any incandescent material. Do not smoke while handling the veterinary medicinal product.
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 (less than 1 in 10,000 animals).

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

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. Repeat the treatment daily for 7 consecutive days.

Care should be taken to avoid spraying into the eyes of the animal.
Presented as a volatile spray, this veterinary medicinal product does not require any massage.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes)

After topical application on the skin at the recommended therapeutic dosage and twice the recommended duration of treatment and at up to a body surface corresponding to the two flanks, from the spine to the mammary chains including the shoulder and the thighs, no systemic effects are observed.
Tolerance studies using 3 and 5 times the recommended dosage for twice the recommended duration of treatment resulted in a reduced capacity for production of cortisol that is fully reversible within 7 to 9 weeks after the end of treatment.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Glucorticosteroids, dermatological preparations.
ATCvet code: QD07AC.

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.

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 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

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Box containing a polyethylene terephtalate (PET) bottle filled with 31 ml or 76 ml of solution, closed with an aluminium screw cap or a white plastic screw cap and a pump spray.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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1ère avenue 2065 m L.I.D.
06516 Carros
FRANCE
0033/4.92.08.73.00
0033/4.92.08.73.48
dar@virbac.fr

8. MARKETING AUTHORISATION NUMBER

EU/2/06/069/001
EU/2/06/069/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09/01/2007
Date of latest renewal: 13/09/2011

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(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Hovione Farmaciencia SA
Sete Casas
2674-506 Loures
Portugal

Name and address of the manufacturer(s) responsible for batch release

VIRBAC SA
1ère Avenue - 2065 m – L.I.D
06516 Carros, France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box with a bottle of 31 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CORTAVANCE 0.584 mg/ml cutaneous spray solution for dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hydrocortisone aceponate 0.584 mg/ml.
Contains no preservative.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

31 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {MM/AA/AA}
Once opened, use by 6 months.

11. SPECIAL STORAGE CONDITIONS

None.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère avenue 2065 m L.I.D.
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/069/002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box with a bottle of 76 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CORTAVANCE 0.584 mg/ml cutaneous spray solution for dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hydrocortisone aceponate 0.584 mg/ml.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

76 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {MM/AA/AA}
Once opened, use by 6 months.

11. SPECIAL STORAGE CONDITIONS

None.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère avenue 2065 m L.I.D.
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/069/001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 76 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CORTAVANCE 0.584 mg/ml cutaneous spray solution for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hydrocortisone aceponate 0.584 mg/ml.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

76 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {MM/AA/AA}
Once opened, use by 6 months.

11. SPECIAL STORAGE CONDITIONS

None.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère avenue 2065 m L.I.D.
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/069/001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 31 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CORTAVANCE 0.584 mg/ml cutaneous spray solution for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Hydrocortisone aceponate 0.584 mg/ml.
Contains no preservative.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

31 ml

4. ROUTE(S) OF ADMINISTRATION

Cutaneous use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

CORTAVANCE 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 and manufacturer:

VIRBAC S.A.
1ère avenue 2065 m L.I.D
06516 Carros
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CORTAVANCE 0.584 mg/ml cutaneous spray solution for dogs

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

Hydrocortisone aceponate 0.584 mg/ml.

Contains no preservative.

4. INDICATIONS

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.

5. CONTRAINDICATIONS

Do not use on cutaneous ulcers.

6. ADVERSE REACTIONS

Transient local reactions at the application site (erythema and/or pruritus) can occur in very rare cases (less than 1 in 10,000 animals).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform you 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. Repeat the treatment daily for 7 consecutive days.
Care should be taken to avoid spraying into the eyes of the animal.
Presented as a volatile spray, this veterinary medicinal product does not require any massage.

In case of conditions requiring an extended treatment, the responsible veterinarian should subject the use of the product to the risk-benefit assessment by the responsible veterinarian.

If signs fail to improve within 7 days, treatment should be re-evaluated by the veterinarian

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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 6 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals

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 animal 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.
In 12 dogs suffering from atopic dermatitis, after topical application on the skin at the recommended therapeutic dosage for 28 to 70 consecutive days, no noticeable effect on the systemic cortisol level was observed.

Total body surface treated should not exceed a surface corresponding for example to a treatment of two flanks from the spine to the mammary chains including the shoulders and the thighs. Otherwise, use only according to the risk-benefit assessment and subject the dog to regular clinical evaluations

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.

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

In case of accidental skin contact, it is recommended to wash thoroughly with water. Wash hands after use.

Avoid contact with eyes. In case of accidental eye contact, rinse with abundant quantities of water. In case of eye irritation, seek medical advice.
In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.

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

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.

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

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

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.

After topical application on the skin at the recommended therapeutic dosage and twice the recommended duration of treatment and at up to a body surface corresponding to the two flanks, from

the spine to the mammary chains including the shoulder and the thighs, no systemic effects are observed.

Tolerance studies using 3 and 5 times the recommended dosage for twice the recommended duration of treatment resulted in a reduced capacity for production of cortisol that is fully reversible within 7 to 9 weeks after the end of treatment.

Box containing a bottle.

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

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