1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cortacare 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.

4.3 Contraindications

Do not use on cutaneous ulcers.

4.4 Special warnings for each target species

The 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 riskbenefit 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, 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. This veterinary medicinal product is 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.

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

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. Prime the pump before administration. 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), if necessary

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 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.

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
B-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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.