cortacare® 0.584 mg/ml

Cutaneous Spray Solution for Dogs

hydrocortisone aceponate

Statement of the active substances and other ingredients

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

Indications

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.

Contraindications

Do not use on cutaneous ulcers.

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.

Target species

Dogs

Dosage for each species, route(s) and method of administration

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.

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

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.
Shelf-life after first opening the container: 6 months

Special warnings

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.
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. 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.
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)
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.

Incompatibilities

None known.

Special precautions for the disposal of unused product or waste material, 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.

Date on which the package leaflet was last approved: August 2018

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

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.

Marketing Authorisation Holder:
Ecuphar NV, Legeweg 157-i, B-8020, Oostkamp, Belgium

Manufacturer responsible for batch release:
Bioglan AB, Borrgatan 31, Malmö, 21124, Sweden

Marketing Authorisation Number:
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UK only:

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To be supplied only on veterinary prescription.

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