Virbac Limited
Telephone: 01359 243243
Website: www.virbac.co.uk

Cortavance

Species:	Dogs
Therapeutic indication:	**Pharmaceuticals: Anti-inflammatory preparations:** Topical
Active ingredient:	Hydrocortisone Aceponate
Product:	CORTAVANCE
Product index:	CORTAVANCE

Qualitative and quantitative composition

Hydrocortisone aceponate 0.584 mg/ml

Pharmaceutical form

Cutaneous spray, solution.

Clinical particulars

Target species

Dogs

Indications for use

For symptomatic treatment of inflammatory and pruritic dermatoses in dogs.

Contra-indications

Do not use on cutaneous ulcers.

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 conditions. 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.

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.

Use during pregnancy or 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 according to the risk-benefit assessment by the responsible veterinarian.

Interactions

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

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 from the area to be treated.

The recommended dosage is 1.52 µg of hydrocortisone aceponate/cm2 of affected skin per day. This dosage can be achieved with two pump spray activations over the 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.

Overdose

After topical application on the skin at the recommended therapeutic dosage and twice the recommended duration of treatment and up to a body surface area 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.

Withdrawal periods

Not applicable.

Pharmacological particulars

Pharmacodynamic properties

The veterinary medicinal product contains the active substance hydrocortisone aceponate.

Hydrocortisone aceponate (HCA) 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.

Pharmacokinetic properties

HCA 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. HCA 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.

Pharmaceutical particulars

Excipients

Propylene glycol methyl ether

Major incompatibilities

None known.

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.

Special precautions for storage

None

Immediate packaging

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

Disposal

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

Marketing Authorisation Number

EU/2/06/069/001

Significant changes

Date of the first authorisation or date of renewal

09.01.2007

Date of revision of the text

09.01.2007

Any other information

Keep treated animals away from fires, other sources of heat and surfaces likely to be affected by the excipient (propylene glycol methyl ether) for at least 30 minutes following spraying or until the fur is totally dry.

Legal category

Legal category: POM-V

GTIN

GTIN description: Cortavance 76ml

GTIN: 3597133039498