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Cortavance (*hydrocortisone aceponate*)

An overview of Cortavance and why it is authorised in the EU

What is Cortavance and what is it used for?

Cortavance is a veterinary medicine used to treat inflamed and itchy skin conditions in dogs. It is also used to treat symptoms of itchy skin in dogs prone to allergies (atopic dermatitis). Cortavance contains the active substance hydrocortisone aceponate.

How is Cortavance used?

The medicine can only be obtained with a prescription. For the treatment of inflamed and itchy skin conditions, Cortavance is given once a day for 7 days. If no improvement is seen after 7 days, the treatment should be re-evaluated by a veterinarian. For treating symptoms of atopic dermatitis, Cortavance is given once a day for at least 14 days, but not more than 28 consecutive days. After 14 days a veterinarian should decide if further treatment is needed.

The medicine is sprayed on the affected area, avoiding the eyes. The pump delivers in two sprays enough medicine to treat an area of about 100 cm^2.

For more information about using Cortavance, see the package leaflet or contact your veterinarian or pharmacist.

How does Cortavance work?

The active substance in Cortavance, hydrocortisone aceponate, is a steroid - a type of substance that helps to reduce inflammation. The steroid is in a special chemical form (a diester) that makes it effective at low doses in skin conditions as the medicine is able to get into and remain longer in the outer layer of the skin.

What benefits of Cortavance have been shown in studies?

Inflamed and itchy skin conditions

For the treatment of inflamed and itchy skin conditions, a field trial compared the treatment of dogs with itchy skin conditions with Cortavance with treatment using a different steroid-containing product.

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Fifty-four dogs were treated with Cortavance and 51 with the comparator, and the results indicated comparable efficacy between Cortavance and the comparator product.

In addition, studies to determine the dose generally supported the chosen dose and the length of treatment. Significant improvement of the skin condition was demonstrated in several studies under controlled conditions, whereas significant reduction of itching was demonstrated in only one of these laboratory studies in which the dogs received treatment against external parasites at the same time.

Atopic dermatitis

Two studies investigated the effects of the medicine in treating symptoms of atopic dermatitis. In the first study, 15 dogs received Cortavance and 13 dogs were given placebo (a dummy treatment), whilst in the second study 25 dogs were treated with Cortavance and 23 dogs with a comparator medicine. The results of the studies showed that treatment of dogs with atopic dermatitis for at least 14 days and up to 28 days with the recommended dose provides significant improvement of skin lesions and pruritus.

What are the risks associated with Cortavance?

Local reactions at the application site such as erythema (skin reddening) and/or itching can occur in very rare cases. Cortavance must not be used on skin ulcers. It must also not be used in dogs that are hypersensitive (allergic) to hydrocortisone aceponate or any of the other ingredients in the medicine.

For the full list of side effects and restrictions of Cortavance, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

The active substance in Cortavance, hydrocortisone aceponate, is potentially pharmacologically active at high doses of exposure.

Wash hands after use. To avoid skin contact, do not handle recently treated animals until the application site is dry. In case of accidental skin contact, avoid hand-to-mouth contact and wash the exposed area immediately with water.

Avoid contact with eyes, as the medicine may cause eye irritation following accidental eye contact. 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 doctor.

To avoid inhalation of the product, spray in a well-ventilated area. The spray is flammable and should not be used next to a naked flame or any incandescent material. Do not smoke when handling this product.

Immediately after use, the bottle should be replaced in the outer carton and in a safe place out of the sight and the reach of children.

Why is Cortavance authorised in the EU?

The European Medicines Agency decided that Cortavance's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Cortavance

Cortavance received a marketing authorisation valid throughout the EU on 9 January 2007.

Further information on Cortavance can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/cortavance

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