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Hydrocortisone aceponate Ecuphar[1] (*hydrocortisone aceponate*)

An overview of Hydrocortisone aceponate Ecuphar and why it is authorised in the EU

What is Hydrocortisone aceponate Ecuphar and what is it used for?

Hydrocortisone aceponate Ecuphar is a corticosteroid 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).

Hydrocortisone aceponate Ecuphar contains the active substance hydrocortisone aceponate and is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance. The reference medicine for Hydrocortisone aceponate Ecuphar is Cortavance.

How is Hydrocortisone aceponate Ecuphar used?

Hydrocortisone aceponate Ecuphar is available as a spray and can only be obtained with a prescription. For the treatment of inflamed and itchy skin conditions, Hydrocortisone aceponate Ecuphar 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, Hydrocortisone aceponate Ecuphar 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 skin 10 cm by 10 cm.

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

How does Hydrocortisone aceponate Ecuphar work?

The active substance in Hydrocortisone aceponate Ecuphar, hydrocortisone aceponate, is a corticosteroid or 'steroid' which acts in the skin cells by stopping the release of chemicals which are involved in inflammation. This reduces swelling, redness and itching. The hydrocortisone in

[1] Previously known as Cortacare

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Hydrocortisone aceponate Ecuphar is in a special chemical form (di-ester) so the medicine is able to get into the outer layer of the skin and remain there for longer. This makes the medicine more effective at low doses in skin conditions.

How has Hydrocortisone aceponate Ecuphar been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Cortavance, and do not need to be repeated for Hydrocortisone aceponate Ecuphar.

As for every medicine, the company provided studies on the quality of Hydrocortisone aceponate Ecuphar. There was no need for 'bioequivalence' studies to investigate whether Hydrocortisone aceponate Ecuphar is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Hydrocortisone aceponate Ecuphar is the same as the reference medicine and when sprayed onto the skin, the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Hydrocortisone aceponate Ecuphar?

Because Hydrocortisone aceponate Ecuphar is a hybrid medicine, its benefits and risks are taken as being the same as the reference medicine's.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Hydrocortisone aceponate Ecuphar, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers. The precautions are the same as for the reference medicine since Hydrocortisone aceponate Ecuphar is a hybrid medicine.

Why is Hydrocortisone aceponate Ecuphar authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Hydrocortisone aceponate Ecuphar has been shown to be comparable to Cortavance. Therefore, the Agency's view was that, as for Cortavance, the benefit of Hydrocortisone aceponate Ecuphar outweighs the identified risk and it can be authorised for use in the EU.

Other information about Hydrocortisone aceponate Ecuphar

Cortacare received a marketing authorisation valid throughout the EU on 27 August 2018.

The name of the medicine was changed to Hydrocortisone aceponate Ecuphar on 20 May 2021.

Further information on Hydrocortisone aceponate Ecuphar can be found on the Agency's website: www.ema.europa.eu/en/medicines/veterinary/EPAR/hydrocortisone-aceponate-ecuphar-previously-cortacare.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 10-2021.