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SCIENCE MEDICINES HEALTH

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Easotic (*hydrocortisone aceponate / miconazole nitrate / gentamicin sulphate*)

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

What is Easotic and what is it used for?

Easotic is a veterinary medicine used to treat dogs that suffer from acute or recurrent episodes of ear infections (otitis externa). It contains three active substances: hydrocortisone aceponate, miconazole nitrate and gentamicin sulphate.

How is Easotic used?

The medicine can only be obtained with a prescription. It is an ear drop suspension to be given once a day for five days. The dose is 1 ml, which is given directly into the ear by one activation of the pump supplied with the bottle. The inside of the ear should be cleaned and dried before treatment and any excess hair cut away.

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

How does Easotic work?

Ear infections in dogs can be caused by bacteria or fungi. They often lead to the ear(s) being inflamed (red, swollen and itchy). Two of the active substances in Easotic, miconazole nitrate and gentamicin sulphate, work against the cause of the infection, while the third one, hydrocortisone aceponate, works on the inflammation.

Hydrocortisone aceponate is a glucocorticosteroid, which is a type of substance that helps to reduce inflammation and itching. Miconazole nitrate is an antifungal that works by preventing the formation of ergosterol, which is an important part of fungal cell walls. Without ergosterol, the fungus is killed or prevented from spreading. Gentamicin sulphate is an antibiotic that belongs to the group aminoglycosides. It acts by preventing bacteria making proteins. This stops the bacteria growing, resulting in their death.

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What benefits of Easotic have been shown in studies?

Easotic has been studied in dogs in both laboratory and field trials. One large field trial was conducted in different centres throughout Europe. In the study, the effectiveness of Easotic was compared with that of ear drops containing three similar active substances in dogs with acute or recurrent bacterial or fungal ear infections. Equal numbers of dogs were assigned to each group, of different breeds, ages, sex and weight.

When used at the recommended dose for five days, Easotic was as effective as the comparator medicine in improving the symptoms of ear infection (redness, swelling, ear discharge and discomfort). The medicine was well tolerated.

What are the risks associated with Easotic?

Mild reddening of the ear has been seen in around 2% of dogs. The use of ear preparations may be associated with damage to hearing. This is usually temporary and happens primarily in older dogs.

Easotic must not be used in dogs that may be allergic to the active substances or any of the other ingredients, if the eardrum is perforated, at the same time as other medicines that can harm the ear, or in dogs with a parasite infection called generalised demodecosis (mange).

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

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

If accidental skin or eye contact occurs, wash immediately with lots of water. If a person accidentally takes the medicine or eye irritation occurs, seek medical advice immediately and show the package leaflet or the label to a doctor.

Why is Easotic authorised in the EU?

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

Other information about Easotic

Easotic received a marketing authorisation valid throughout the EU on 20 November 2008.

Further information on Easotic can be found on the Agency's website:

ema.europa.eu/medicines/veterinary/EPAR/easotic.

This overview was last updated in 11-2020.