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Posatex (*orbifloxacin / mometasone furoate / posaconazole*)

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

What is Posatex and what is it used for?

Posatex is a veterinary medicine used to treat dogs that suffer from acute or recurrent episodes of ear infections (otitis externa) caused by bacteria or fungi. It contains the active substances orbifloxacin, mometasone furoate and posaconazole.

How is Posatex used?

Posatex is available as an ear drop suspension and can only be obtained with a prescription.

It is given once a day for seven days. The number of ear drops to use depends on the weight of the dog and varies from two to eight. The inside of the ear should be cleaned and dried before treatment.

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

How does Posatex 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 Posatex, orbifloxacin and posaconazole, work against the cause of the infection, while the third one, mometasone furoate, works on the inflammation.

Orbifloxacin is an antibiotic that belongs to the group fluoroquinolones. It works by blocking an enzyme called 'DNA gyrase', which is important in allowing bacteria to make copies of their DNA. By blocking DNA gyrase, orbifloxacin prevents the bacteria from making DNA and stops them making proteins and growing, resulting in their death. Posaconazole is an antifungal that belongs to the group triazoles. It 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. Mometasone furoate is a steroid, which is a type of substance that helps to reduce inflammation.

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What benefits of Posatex have been shown in studies?

Posatex has been studied in dogs in both laboratory and field studies. In two large field studies, one conducted in Europe and one in the United States, the effectiveness of Posatex was compared with that of ear drops containing three similar active substances. Equal numbers of dogs were assigned to each group, of different breeds, ages, sex and weight.

The studies showed that, after 7 days of treatment, Posatex was as effective as the comparator medicine in improving the symptoms of ear infections (redness, swelling, ear discharge, discomfort) in dogs with acute or recurrent bacterial or fungal infections.

What are the risks associated with Posatex?

Mild reddening of the ear has been observed. The use of ear preparations may be associated with damage to hearing, usually temporary and primarily in older dogs.

Posatex must not be used if the eardrum is perforated; it must also not be used during whole or part of the pregnancy. It must not be used in case of hypersensitivity (allergy) to the active substances or to corticosteroids, to other azole antifungal agents or to other fluoroquinolones.

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

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 Posatex, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers. This veterinary medicine has been developed especially for dogs and is not for use in humans. If a person accidentally takes the medicine, seek medical advice immediately and show the package leaflet or the label to a doctor. If accidental skin contact occurs, wash immediately with lots of water.

Why is Posatex authorised in the EU?

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

Other information about Posatex

Posatex received a marketing authorisation valid throughout the EU on 23 June 2008.

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

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