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EPAR summary for the public

Osurnia

Terbinafine, florfenicol and betamethasone

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is Osurnia?

Osurnia is a veterinary medicine that contains three active substances: terbinafine, florfenicol and betamethasone acetate. It is available as a gel to be given into the ear.

What is Osurnia used for?

Osurnia is used to treat short lived or recurrent ear infections (otitis externa) due to *Staphylococcus pseudintermedius* (a bacterium) and *Malassezia pachydermatitis* (a yeast). Ear infections in dogs can be caused by bacteria or yeasts/fungi. They often lead to the ear(s) being inflamed (red, swollen and sore) or painful.

The contents of one tube of gel are given into each infected ear. The inside of the ear should be cleaned and dry before treatment. Treatment is repeated after one week, but the ears should not be cleaned for the second dose.

How does Osurnia work?

Two of the active substances in Osurnia terbinafine and florfenicol, act against possible causes of infection. Terbinafine kills fungi by blocking the formation of ergosterol, an important part of fungal cell walls. Florfenicol is an antibiotic which works by blocking protein formation in bacterial cells. The third

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active ingredient, betamethasone acetate, is a corticosteroid, a medicine that reduces inflammation and pain.

How has Osurnia been studied?

Three field studies were conducted in dogs with otitis externa caused by bacterial or fungal infections, investigating the effect of treatment following cleaning out of the ear with saline solution; treatment with two doses of Osurnia, one week apart, was compared with another comparable ear medicine or with placebo (dummy treatment).

The first was an EU study involving 286 dogs in which 148 dogs given Osurnia were compared with 138 dogs treated with another ear medicine containing miconazole (a medicine against fungal infections), gentamicin (an antibiotic) and hydrocortisone aceponate (a corticosteroid) for five consecutive days. The other studies took place in the USA and Japan respectively. The US study involved 284 dogs, 190 of which were treated with Osurnia, while 90 dogs received placebo gel (dummy treatment). The Japanese study involved 71 dogs; 49 dogs were treated with Osurnia and 22 dogs with another ear medicine containing clotrimazole (for fungal infections), gentamicin (an antibiotic) and betamethasone valerate (corticosteroid).

The main measure of effectiveness in the EU and Japanese studies was the reduction in severity of otitis externa 28 days after initial treatment; in the US study clinical success was measured after 45 days.

What benefit has Osurnia shown during the studies?

In the EU study Osurnia was as effective as the comparator medicine with both treatments resulting in 63% reduction in severity of otitis externa.

In the US study the Osurnia treated dogs had a success rate of 65% which was significantly higher than the placebo treated dogs with a success rate of 44%. The relatively high rate of success for the placebo might have been due to the effect of cleaning the ear beforehand and because the way the product was formulated produced a protective film of gel on the surface of the ear canal.

In the Japanese study Osurnia was as effective as the other medicine with 78% improvement in otitis externa in both treatment groups.

What is the risk associated with Osurnia?

Osurnia must not be used if the ear drum is perforated or in dogs with generalised demodicosis (mange caused by the mite *Demodex canis*). Osurnia must also not be used in pregnant or breeding animals.

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

If accidental exposure to the eyes occurs, the eyes should be rinsed with water and in case of accidental exposure to the skin, the skin should be washed with soap and water.

If the veterinary medicine is accidentally swallowed, immediate medical advice should be sought and the package leaflet or label shown to the doctor.

Why has Osurnia been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Osurnia exceed the risks for the approved indications and recommended that Osurnia be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about Osurnia:

The European Commission granted a marketing authorisation valid throughout the European Union, for Osurnia on 31 July 2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in June 2014.