EMA/560411/2019
EMEA/V/C/004735

Neptra (florfenicol / terbinafine / mometasone)

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

What is Neptra and what is it used for?

Neptra is a veterinary medicine used to treat dogs with short lived or recurrent ear infections (otitis externa) caused by two organisms: *Staphylococcus pseudintermedius* (a bacterium) and *Malassezia pachydermatitis* (a yeast). Neptra contains three active substances: florfenicol, terbinafine and mometasone.

How is Neptra used?

The medicine is available as ear drops and can only be obtained with a prescription.

The contents of one tube are given into each infected ear. The inside of the ear should be cleaned and dry before treatment. A single treatment is required however the full effect may only be seen 28 days later.

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

How does Neptra work?

Two of the active substances in Neptra, florfenicol and terbinafine, act against possible causes of infection. Florfenicol is an antibiotic which works by blocking the production of proteins, which are essential components of bacterial cell walls. Terbinafine kills fungi by blocking the formation of ergosterol, an important part of fungal cell walls. The third active substance, mometasone, is a corticosteroid, a medicine that reduces inflammation and pain associated with the infection.

What benefits of Neptra have been shown in studies?

In a field study in Europe involving dogs with ear infections with both *Staphylococcus pseudintermedius* and *Malassezia pachydermatitis* 43 Neptra treated dogs had their signs of infection reduced by 71% after 28 days which was as effective as the comparator group of 45 dogs, treated with another veterinary medicine authorised for ear infections, for which the reduction was 74%.

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In a field study in the US involving dogs again with ear infections due to both organisms, 67 dogs treated with Neptra had a reduction in clinical score of 77% over 30 days. This was more effective than the control group of 27 dogs, which received a placebo (dummy treatment) and for which the reduction was 49%.

What are the risks associated with Neptra?

Side effects with Neptra occur very rarely, with the most often reported (which may affect up to 1 in 10,000 dogs) being whining, head shaking, nystagmus (uncontrolled eye movements), vomiting, inner ear disorders causing imbalance, loss of appetite, hyperactivity and application site pain and inflammation shortly after applying the medicine.

Neptra must not be used in dogs who are allergic to the active substances, to other corticosteroids or to any of the other ingredients. It must also not be used if the ear drum is perforated, in dogs with generalised demodectic mange (skin infestation caused by a specific type of mite) or in pregnant or breeding animals.

For the full list of restrictions, see the package leaflet.

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

Neptra can cause serious eye irritation if it accidentally gets into the eyes when the dog shakes its head during or just after application. It is therefore recommended that this medicine is applied only by veterinarians or under their close supervision and that measures are taken to reduce the risk (e.g. wearing safety glasses during treatment, massaging the ear canal well after application to ensure even distribution of product, restraining the dog after application). In case of accidental eye exposure, the eyes should be flushed thoroughly with water for 10 to 15 minutes. If symptoms develop, medical advice should be sought and the package leaflet or the label shown to the doctor.

Although no potential for skin irritation was indicated by studies, skin contact should be avoided. In case of accidental skin contact, exposed skin should be thoroughly washed with water.

Neptra may be harmful after swallowing. Avoid swallowing the product or accidentally transferring it from hand to mouth. In case of accidental swallowing medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

Why is Neptra authorised in the EU?

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

Other information about Neptra

Neptra received a marketing authorisation valid throughout the EU on 10 December 2019.

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

This overview was last updated in October 2019.