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EPAR summary for the public

Fungitraxx

Itraconazole

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 Fungitraxx?

Fungitraxx is a veterinary medicine that contains the active substance itraconazole. It is available as a solution to be given by mouth.

What is Fungitraxx used for?

Fungitraxx is used to treat ornamental birds with two types of fungal infections of the respiratory tract (aspergillosis and candidiasis). It can be used to treat aspergillosis in cockatoos, parrots, parakeets, budgerigars, falcons, hawks, owls and swans, and also to treat candidiasis in cockatoos, parrots, parakeets and budgerigars. It is given by mouth at a dose of 5 to 10 mg itraconazole per kg bodyweight each day for 8 weeks for aspergillosis, and 10 mg per kg daily for 2 weeks for candidiasis.

How does Fungitraxx work?

Itraconazole is an antifungal medicine. It works by blocking the production of a compound in the fungus called ergosterol which is an important part of fungal cell membranes. By blocking production of this compound, itraconazole leads to the breakdown of the fungal cells, killing the fungus or preventing it from spreading.

How has Fungitraxx been studied?

A field study was performed with 62 birds with aspergillosis (cockatoos, parrots, parakeets, budgerigars, falcons, hawks, owls and swans) and 18 birds with candidiasis (cockatoos, parrots, parakeets and budgerigars). For aspergillosis, birds were included if the presence of *Aspergillus* fungi in air sacs was confirmed and, for candidiasis, birds were included if clinical signs of candidiasis were present and infection was confirmed. The measure of effectiveness was disappearance of sleepiness, reduced appetite and loss of bodyweight and disappearance of aspergillosis or candidiasis.

What benefit has Fungitraxx shown during the studies?

The field study showed that Fungitraxx is effective in treating aspergillosis (with 56 out of 62 birds successfully treated) and candidiasis (with all birds successfully treated).

What is the risk associated with Fungitraxx?

Fungitraxx must not be used in birds intended for human consumption.

Vomiting, loss of appetite and weight loss are common in treated birds (seen in up to 1 in 10 birds). These effects are usually mild and related to the dose, and can be managed by reducing the dose or if necessary stopping treatment.

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

Hands and exposed skin should be washed after using Fungitraxx. In case of accidental contact with the eyes, they should be rinsed thoroughly with water.

In the case of accidental ingestion the mouth should be rinsed, medical advice sought immediately and the package leaflet or label shown to the doctor.

Some fungal infections of birds can also infect humans. When handling birds infected with aspergillosis, latex gloves and a mask should be worn to prevent the disease being transmitted to the handler. If suspected signs of disease (such as lumps or red pimples on the skin, or symptoms such as coughing or wheezing) appear in people a doctor should be consulted.

Why has Fungitraxx been approved?

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

Other information about Fungitraxx:

The European Commission granted a marketing authorisation valid throughout the European Union, for Fungitraxx on 12/03/2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2014.