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EPAR summary for the public

Zolvix

Monepantel

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 Zolvix?

Zolvix is a medicine that contains the active substance monepantel. Zolvix is available as an oral solution (25 mg/ml).

What is Zolvix used for?

Zolvix is used for the treatment and control of worm infections of the gut and associated diseases in sheep. Zolvix is effective against a wide range of worm species.

Zolvix is given as a single dose of 2.5 mg per kilogram bodyweight. The amount to use is calculated based on the weight of the sheep. The oral solution is given directly on the back of the tongue.

How does Zolvix work?

Monepantel, is an anthelmintic, a substance that is active against helminths. Helminths, also known as nematodes, are worm-like parasites that live in the gut of animals. Monepantel blocks part of a receptor, the nicotinic acetylcholine receptor, that is specific to the nematodes. This causes paralysis and death of the worms. Monepantel is effective against nematodes resistant to other anthelmintics.

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How has Zolvix been studied?

A number of laboratory studies and field trials in various countries were performed. Two main studies were carried out, one in Europe and one in New Zealand, in sheep suffering from a range of nematode infections. The New Zealand study and some additional studies compared the effectiveness of Zolvix to other anthelmintics. In the studies, the effectiveness of Zolvix was measured by looking for parasite eggs in the sheep faeces at different time points during the trials.

What benefit has Zolvix shown during the studies?

The studies showed that Zolvix is effective against infections of all of the major gastrointestinal nematodes, including effectiveness against strains of parasites resistant to the currently available broad-spectrum anthelmintics.

What is the risk associated with Zolvix?

The effectiveness of Zolvix has not been established in sheep weighing less than 10 kg and safety has not been established in sheep weighing less than 10 kg or under two weeks of age. To help delay the development of resistance, users are advised to check the success of the treatment by examining the sheep's clinical appearance, or by testing whether any parasite eggs can be found in the faeces.

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

Users who are administering this medicine to sheep should wear protective gloves. In case of accidental spillage onto skin or into eyes, the area should be washed immediately with water. Any contaminated clothes should be removed. In case of accidental ingestion medical advice should be sought immediately and the package leaflet or the label shown to the doctor. The user must not eat, drink or smoke whilst handling the product and hands and exposed skin should be washed after handling the product.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for human consumption or milk used for human consumption. The withdrawal period for sheep for meat and offal is seven days. Zolvix is not authorised for use in lactating animals producing milk for human consumption.

Why has Zolvix been approved?

The CVMP concluded that the benefits of Zolvix exceed the risks for the approved indications and recommended that Zolvix be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about Zolvix:

The European Commission granted a marketing authorisation valid throughout the European Union, for Zolvix on 4 November 2009. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in November 2013.