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Elanco UK AH Limited

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ZOLVIX 25 mg/ml oral solution for sheep

Species: Sheep

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Anthelmintics for sheep

Active ingredient: Monepantel

Product:ZOLVIX 25 mg/ml oral solution for sheep

Product index:ZOLVIX 25 mg/ml oral solution for sheep

Sheep - meat:7 days

Withdrawal notes: Not authorised for use in animals producing milk for human consumption.

Incorporating:

Qualitative and quantitative composition

Active substance:

Each ml contains 25 mg of monepantel

Excipients:

Qualitative composition of excipients and other constituents
RRR-α-tocopherol
Beta-carotene
Maize oil
Propylene glycol
Macrogolglycerol hydroxystearate
Polysorbate 80
Propylene glycol monocaprylate

Propylene glycol dicaprylocaprate

Orange clear oral solution

Pharmaceutical form

Oral solution.

Orange clear solution.

Clinical particulars

Target species

Sheep

Indications for use, specifying the target species

ZOLVIX oral solution is a broad spectrum anthelmintic for the treatment of gastro- intestinal nematode infections and associated diseases in sheep including lambs, hoggets, breeding rams and ewes.

Spectrum of activity includes fourth larvae and adults of:

*Haemonchus contortus**

*Teladorsagia circumcincta**

*Teladorsagia trifucrcata**

*Teladorsagia davtiani**

*Trichostrongylus axei**

Trichostrongylus colubriformis

Trichostrongylus vitrinus

Cooperia curticei

Cooperia oncophora

Nematodirus battus

Nematodirus filicolllis

Nematodirus spathiger

Chabertia ovina

Oesophagostomum venulosum

*including inhibited larvae

Contraindications

None.

Special warnings for each target species

The efficacy has not been established in sheep weighing less than 10 kg.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific flock should be sought from the responsible veterinarian.

Isolated cases of resistance against monepantel have been identified within the European Union.

The use of this product should take into account local information about susceptibility of the target parasites, where available.

In order to help delay the development of resistance, users are advised to check the success of the treatment (e.g. clinical appearance, faecal egg counts). It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test). Where the results of the tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Special precautions for use

<u>Special precautions for use in animals</u>

The safety has not been established in sheep weighing less than 10 kg or under 2 weeks of age.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals</u>

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

In case of accidental spillage onto skin or into eyes, wash immediately with water. Take off any contaminated clothes. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Do not eat, drink or smoke whilst handling the veterinary medicinal product. Wash hands and exposed skin after handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

Adverse reactions (frequency and seriousness)

Sheep:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 'Contact details' of the package leaflet.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

The veterinary medicinal product can be used in pregnant and lactating ewes.

Fertility:

The veterinary medicinal product can be used in breeding sheep.

Interaction with other medicinal products and other forms of interaction

None known.

Amounts to be administered and administration route

The dose is 2.5 mg/kg bodyweight of monepantel.

The veterinary medicinal product is administered as a single treatment.

However, the administration may be repeated. The need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

It is recommended that the veterinary medicinal product is used not more than twice in one year.

Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

The use of suitably calibrated measuring equipment is recommended. Accuracy of the dosing device should be thoroughly checked.

To assure complete swallowing of this low volume solution, administer orally on the back of the tongue. Drenching equipment should be cleaned after use.

Dose table:

Body weight, kg	dose, ml
10 - 15	1.5
16 - 20	2
21 - 25	2.5
26 - 30	3
31 - 35	3.5
36 - 40	4
41 - 50	5
51 - 60	6
61 - 70	7
> **70**	1 ml for each additional 10 kg

Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse effects were observed after a 10-fold overdose.

Withdrawal period(s)

Meat and offal: 7 days.

Not authorised for use in animals producing milk for human consumption.

Pharmacological particulars

Pharmacotherapeutic group: anthelmintics. ATCvet code: QP52AX09.

Pharmacodynamic properties

NI SPC ONLY - Monepantel is an anthelmintic belonging to the amino-acetonitrile derivative (AAD) cla
nematode specific nicotinic acetylcholine receptor sub-unit Hco-MPTL-1. This is the first biological fu
1 receptor and therefore monepantel is effective against nematodes resistant to other anthelmintic cl

ZOLVIX was shown to be effective against strains of gastro-intestinal parasites, listed in section 3.2, resistant to (pro)benzimidazoles, levamisole, morantel, macrocyclic lactones and *H. contortus* strains resistant to salicylanilides. In addition, the product was shown to be effective against 4th stage larvae of a strain of *H. contortus* in a laboratory study where a combination of abamectin with derquantel was not effective.

Pharmacokinetic particulars

After oral administration monepantel is readily absorbed and oxidised to a sulfone metabolite. Peak blood concentrations are reached within a day. Afterwards blood concentrations decrease with a half life of about five days. Excretion is mainly via the faeces but also via the urine. Feeding or fasting before or shortly after treatment does not influence efficacy.

Pharmaceutical particulars

List of excipients

RRR-α-tocopherol

Beta-carotene

Maize oil

Propylene glycol

Macrogolglycerol hydroxystearate

Polysorbate 80

Propylene glycol monocaprylate

Propylene glycol dicaprylocaprate

Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 1 year

Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

Nature and composition of immediate packaging

Fluorinated high density polyethylene (HDPE) bottles with a polypropylene cap.

Pack sizes: carton box containing 1 x 250 ml, 500 ml, 1 l, 2.5 l, or 5 l bottle.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

NI SPC ONLY

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materia local requirements and with any national collection systems applicable to the veterinary medicinal pr

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Marketing Authorisation Holder (if different from distributor)

Elanco GmbH

Heinz-Lohmann-Str. 4

27472 Cuxhaven

Germany

Marketing Authorisation Number

UK (Great Britain): Vm 52127/5029

UK (Northern Ireland): EU/2/09/101/001-010

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 04/11/2009

Date of revision of the text

August 2023

Any other information

Veterinary medicinal product subject to prescription.

Legal category

Legal category:POM-VPS

GTIN

GTIN description:ZOLVIX 25 mg/ml oral solution for sheep 0.5L

GTIN:05037694091156

GTIN description:ZOLVIX 25 mg/ml oral solution for sheep 1L

GTIN:05037694053314

GTIN description:ZOLVIX 25 mg/ml oral solution for sheep 2.5L

NOAH Compendium

GTIN:05037694053338