SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZOLVIX 25 mg/ml oral solution for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Monepantel 25 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution
Orange clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep.

4.2 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 trifurcata**
*Teladorsagia davtiani**
*Trichostrongylus axei**
Trichostrongylus colubriformis
Trichostrongylus vitrinus
Cooperia curticei
Cooperia oncophora
Nematodirus battus
Nematodirus filicollis
Nematodirus spathiger
Chabertia ovina
Oesophagostomum venulosum

*including inhibited larvae

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

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

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

iii) Special precautions for the protection of the environment:

Not applicable

4.6 Adverse reactions (frequency and seriousness)

Target species: sheep

None.

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 the last section of the package leaflet for contact details.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) 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 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

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

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

4.11 Withdrawal period(s)

Meat and offal: 7 days.
Not authorised for use in animals producing milk for human consumption.

5. PHARMACOLOGICALPROPERTIES

Pharmacotherapeutic group: anthelmintics

ATC Vet Code: QP52AX09

5.1 Pharmacodynamic properties

ZOLVIX was shown to be effective against strains of gastro-intestinal parasites, listed in section 4.2, 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.

5.2 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

RRR-α-tocopherol
Beta-carotene
Maize oil
Propylene glycol
Macrogolglycerol hydroxystearate
Polysorbate 80
Propylene glycol monocaprylate
Propylene glycol dicaprylocaprate

6.2 Major Incompatibilities

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

6.3 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

6.4 Special precautions for storage

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

6.5 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.

6.6 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco GmBH
Heinz-Lohmann Strasse 4
Groden, Cuxhaven
Lower Saxony, 27472
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 52127/5029

9. DATE OF FIRST AUTHORISATION

4 November 2009

10. DATE OF REVISION OF THE TEXT

August 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 29 August 2023