PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZOLVIX 25 mg/ml oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 25 mg of monepantel

3. PACKAGE SIZE

250 ml
500 ml
1 l
2.5 l
5 l

4. TARGET SPECIES

Sheep

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period(s): Meat and offal: 7 days.
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 1 year.
Once opened used by:….

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
Groden
D-27472 Cuxhaven
Germany

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5029

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS (To be supplied only on veterinary prescription)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE HDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZOLVIX 25 mg/ml oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 25 mg of monepantel

3. TARGET SPECIES

Sheep

4. ROUTES OF ADMINISTRATION

Oral Use

5. WITHDRAWAL PERIODS

Withdrawal period(s): Meat and offal: 7 days.
Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 1 year.
Once opened use by:…..

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
Groden
D-27472 Cuxhaven
Germany

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

250 ml
500 ml
1 l
2.5 l
5 l

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-VPS (To be supplied only on veterinary prescription)

15. MARKETING AUTHORISATION NUMBER

Vm 52127/5029

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZOLVIX 25 mg/ml oral solution for sheep

2. COMPOSITION

Each ml of ZOLVIX orange clear oral solution contains 25 mg of monepantel.

3. TARGET SPECIES

Sheep

4. INDICATIONS FOR USE

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**
*T. trifurcata**
*T. davtiani**
*Trichostrongylus axei**
T. colubriformis
T. vitrinus
Cooperia curticei
C. oncophora
Nematodirus battus
N. filicollis
N. spathiger
Chabertia ovina

Oesophagostomum venulosum

*Including inhibited larvae

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

Special warnings:

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.

The efficacy has not been established in sheep weighing less than 10 kg.
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 test(s) 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 safe use in the target species:
The safety has not been established in sheep weighing less than 10 kg or under 2 weeks of age.

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.

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:
No interaction with other medicinal products and other forms of interaction are known.

Overdose (symptoms, emergency procedures, antidotes):
No adverse effects were observed after a 10-fold overdose.

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

7. ADVERSE EVENTS

Sheep

None.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose table

Bodyweight, 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 kg**	1 ml for each additional 10 kg

Administer orally with a suitable dose device.

9. ADVICE ON CORRECT ADMINISTRATION

The dose rate 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.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle label after "Exp". The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 1 year.

Once the immediate package is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5029

Pack sizes:
Cardboard box with 1 X 250 ml, 500 ml, 1 l, 2.5 l, or 5 l HDPE bottle
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

August 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov,uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann-Strasse 4
Groden
D-27472 Cuxhaven
Germany

PV.GBR@elancoah.com

Manufacturer responsible for batch release:

Argenta Dundee Limited
Kinnoull Road
Dunsinane Industrial Estate
Dundee DD2 3XR
United Kingdom

Elanco France S.A.S
26 Rue de la Chapelle
F-68330 Huningue
France

17. OTHER INFORMATION

Monepantel is an anthelmintic belonging to the amino-acetonitrile derivative (AAD) class of molecules.

ZOLVIX was shown to be effective against strains of gastro-intestinal parasites, listed in section 4, 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.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

Approved 29 August 2023