ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZOLVIX 25 mg/ml oral solution for sheep

2. 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

3. CLINICAL INFORMATION

3.1 Target species

Sheep

3.2 Indications for use for each 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

3.3 Contraindications

None.

3.4 Special warnings

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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

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.

3.7 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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AX09

4.2 Pharmacodynamics

Monepantel is an anthelmintic belonging to the amino-acetonitrile derivative (AAD) class of molecules. Monepantel acts on the nematode specific nicotinic acetylcholine receptor sub-unit Hco-MPTL-1. This is the first biological function to be described for the Hco-MPTL-1 receptor and therefore monepantel is effective against nematodes resistant to other anthelmintic classes.

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 4^{th} stage larvae of a strain of *H. contortus* in a laboratory study where a combination of abamectin with derquantel was not effective.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

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 materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/101/002
EU/2/09/101/004
EU/2/09/101/006
EU/2/09/101/008
EU/2/09/101/010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 04/11/2009

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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 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. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
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.

9. SPECIAL STORAGE PRECAUTIONS

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 OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/09/101/002 250 ml
EU/2/09/101/004 500 ml
EU/2/09/101/006 1 l
EU/2/09/101/008 2.5 l
EU/2/09/101/010 5 l

15. BATCH NUMBER

Lot {number}

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 SUBSTANCES

Each ml contains 25 mg of monepantel

3. TARGET SPECIES

Sheep

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
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.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

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 warnings

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:
Can be used in pregnant and lactating ewes.

Fertility:
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:
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 known.

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: {national system details}.

8. Dosage for each species, routes 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 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.

10. Withdrawal periods

Withdrawal period:
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.

12. Special precautions for disposal

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 materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/09/101/002
EU/2/09/101/004
EU/2/09/101/006
EU/2/09/101/008
EU/2/09/101/010

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

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PV.XXI@elancoah.com

Manufacturer responsible for batch release:
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 'Indications for use', 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.