Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 5% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance

Triclabendazole	50	mg

Excipients

Methyl Parahydroxybenzoate (E218)	1.1	mg
Propyl Parahydroxybenzoate (E216)	0.24	mg
Benzoic Acid (E210)	1.0	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension.
White to cream-coloured suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Ovines.

4.2 Indications for use, specifying the target species

For the treatment and control of adult, immature and early immature stages of liver fluke susceptible to triclabendazole.
Target Species: *Fasciola hepatica*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance.

4.4 Special warnings for each target species

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (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.

4.5 Special precautions for use

Special precautions for use in animals

Only use for liver fluke strains susceptible to Triclabendazole. Clean drenching equipment before and after use. Where a dosing gun is used to administer the product, care must be taken to avoid the occurrence of dosing gun pharyngitis.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

This product may be given to pregnant and lactating animals. See section 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Fasinex is given as an oral drench and is suitable for most types of automatic drenching guns. Fasinex can safely be given to young, pregnant or stressed sheep.
The recommended dose rate is 10 mg per kg bodyweight.
Practical Dosage Guide: 2 ml per 10 kg bodyweight.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.
Use properly calibrated dosing equipment.

Dosing Programme:
Areas of heavy fluke infection (the western seaboard)
In areas such as these where traditionally more than 4 treatments per year have been administered, Novartis recommend that under veterinary advice, 3 spring/summer treatments should be administered and one in November instead of autumn/winter treatments. In situations where stock are outwintered another dose in January may be required.

Jan - Feb - Mar - Apr - May - Jun - Jul - Aug - Sept - Oct - Nov - Dec
* * * * *
Dose Dose Dose Dose Dose

These treatment times are guidelines and should be customised under veterinary advice for each individual farm. Spring/summer treatments prevent the flukes entering the mud snail and so the life cycle is broken.
Every animal on the same land including cattle should be included in the programme and all animals should be treated on the same day. When cattle are included in the programme they should be treated with Fasinex 10%.
All bought in animals should be dosed before joining the main flock.

Areas of Average Fluke Infection:
Dose all sheep on fluke infected pastures at regular intervals of 8 to 10 weeks throughout the fluke season, usually from September to January/February.
Guidance from the Department of Agriculture fluke forecast may be useful when deciding to start treatment.

Treatment of Acute Outbreaks:
The flock should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals.
If a preventative fluke dosing is employed the occurrence of acute fluke is greatly reduced.

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

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

A single oral dose of 150-200 mg triclabendazole/kg of live bodyweight may lead to side effects such as unsteady gait, dullness and reduced appetite. These side effects are slight and last 1 to 3 days. An antidote is not known.

4.11 Withdrawal period(s)

Meat and offal: 55 days
Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles.
ATCvet code: QP52AC01

5.1 Pharmacodynamic properties

The mode of action of triclabendazole is not known but is probably different from that of other benzimidazoles as it does not exert its activity by association with tubulin. Triclabendazole and its sulfoxide metabolite are anthelmintically active.

5.2 Pharmacokinetic particulars

About half of the orally administered dose of triclabendazole is absorbed from the gastrointestinal tract. Very rapidly, absorbed triclabendazole is almost completely oxidised to its sulfoxide and sulfone. Triclabendazole sulfoxide reaches peak concentrations (ca. 15ppm) 20 hours after administration of FASINEX and the sulfone reaches peak concentrations (ca. 10ppm) 30 to 32 hours after administration. Both metabolites bind strongly to plasma proteins, particularly albumin.

Metabolites are excreted via the bile mainly as conjugates. More than 90% of the total dose of FASINEX is excreted in the faeces, about 2% in the urine and less than 1% in the milk. The elimination is virtually complete by 10 days after administration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose and Carmellose Sodium
Povidone
Disodium Phosphate Dodecahydrate
Methyl Parahydroxybenzoate (E218)

Propyl Parahydroxybenzoate (E216)
Benzoic Acid (E210)Purified Water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Store below 25°C.
Protect from frost.
Protect from light.

6.5 Nature and composition of immediate packaging

0.8, 2.2 and 12 litre HDPE containers.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1999
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

June 2018