Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 10% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml comtains:		
Active Substance		
Triclabendazole	100	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

Bovines.

4.2 Indications for use, specifying the target species

For the treatment and control of adult, immature and early immature liver fluke.
Target parasite species: *Fasciola hepatica*

4.3 Contraindications

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

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

Shake container well before use.
Only use for liver fluke strains susceptible to Triclabendazole.
If lack of efficacy is suspected, seek veterinary advice.
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 known.

4.7 Use during pregnancy, lactation or lay

The product is safe for use during pregnancy and lactation. 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 cattle. However, Fasinex is not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

The recommended dose rate is 12 mg per kg bodyweight.
Practical Dosage Guide: 6 ml per 50 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.

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

Dosing Programme:
Areas of heavy fluke infection (the western seaboard)
On land where sheep are being treated according to the preventative programme and where cattle are also grazing these areas, the product should be administered to the cattle on the same treatment dates as the sheep.

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 sheep should be included in the programme and all animals should be treated on the same day. Fasinex 5% should be used in sheep.
All bought in animals should be dosed before joining the main flock.

Areas of Average Fluke Infection:
Outwintered Cattle:
Dose all cattle exposed to fluke infected pastures at regular intervals of 8-10 weeks throughout the fluke season.

Housed Cattle:
Dose cattle, which have grazed fluke infected pasture, in the Autumn and at the time of or shortly after housing.
Dosing should start at the beginning of the fluke season when animals are still outdoors.

Bought in Cattle:
Dose before joining the main herd.

Treatment of acute outbreaks:
The herd should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals.

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: 46 days
Not authorised for use in cattle producing milk for human consumption, including during the dry period. Do not use during the last trimester of pregnancy in heifers which are 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 properties

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 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

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 Europe Ltd
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10397/001/002

9 DATE OF THE 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

October 2016