SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 10% Oral Suspension for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active substance:	
Triclabendazole	10.000% w/v
Excipient(s):	
Antimicrobial preservatives:	
Methyl hydroxybenzoate	0.110% w/v
Propyl hydroxybenzoate	0.024% w/v
Benzoic acid	0.100% w/v

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
A cream coloured aqueous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Non-lactating cattle.

4.2 Indications for use, specifying the target species

For the treatment and control of liver fluke infections in non-lactating cattle caused by all stages of triclabendazole-susceptible *Fasciola hepatica* from 2 week old immature to adult fluke.

4.3 Contraindications

None.

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 form 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 (if any).

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 test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a difference mode of action should be used.

Resistance to triclabendazole has been reported in *Fasciola hepatica* in cattle in a number of countries, including ones in the EU. Therefore, the use of this product should be based on local epidemiological information about susceptibility of *F. hepatica* and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

i. Special precautions for use in animals

Assess bodyweight as accurately as possible before calculating dose.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary adviser. Efficacy of this product against liver fluke is reduced if triclabendazole-resistant strains are present.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Do not eat, drink or smoke whilst handling the product.
Wash hands and exposed skin before meals and after work.
In case of accidental spillage onto skin or eyes, wash immediately with water. Take off any contaminated clothing immediately.

iii. Other precautions

None.

4.6. Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not authorised for use in cattle producing milk for human consumption including during the dry period.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Clean drenching equipment before and after use.
Use unaltered product from the original container.

Administration route

For oral administration. Dosage rate 12 mg triclabendazole/kg bodyweight (3.0 ml Fasinex 10% / 25 kg bodyweight).

Shake the container thoroughly before use.
Most types of automatic drenching gun may be used.

Routine herd treatment (high risk fluke areas)

As a guide, dose all cattle exposed to fluke infested pastures preventatively at regular intervals of 10 weeks from March / April through to October / November. In situations where stock are outwintered, a dose in January may also be required. All animals grazing the pasture should be treated at these times. Any bought-in cattle should be dosed before joining the main herd. Veterinary advice should be sought with regards to specific preventative dosing regimes.

Routine herd treatment (moderate risk fluke areas)

Dose all cattle exposed to fluke-infested pastures at regular intervals of 10 weeks throughout the fluke season, usually from September to January / February. An additional preventative treatment in the spring will assist in reducing the amount of new infection on pasture in the following autumn. Cattle bought in from fluke risk areas should be treated before joining the main herd.

Interwintering: where cattle are interwintered, a single dose of FASINEX should be given 2 weeks after housing.

Treatment of sub-acute and acute outbreaks: affected cattle, usually young animals, should be treated immediately after diagnosis is reached. Veterinary advice should be sought for subsequent dosing intervals.

To ensure administration of correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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 over-dosing.

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

No treatment specified.

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 56 days from the last treatment.
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 PROPERTIES

Pharmacotherapeutic group: Anthelmintic, benzimidazoles and related substances.

ATC Vet Code: QP52 AC01

5.1 Pharmacodynamic properties

Triclabendazole is a flukicide.

5.2 Pharmacokinetic particulars

Majority of oral dose in rats, sheep, goats and rabbits is eliminated in faeces after 6-10 days as unchanged drug or products of biliary excretion. Urinary excretion is minimal. Sulphone, sulphoxide, ketone and 4-hydroxy triclabendazole derivatives are the main metabolites identified in plasma.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate
Propyl hydroxybenzoate
Benzoic acid
Povidone K30
Microcrystalline cellulose
Carmellose sodium
Sodium phosphate
Water, demineralised

6.2 Incompatibilities

None.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light. Protect from freezing.
Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

Packs of 0.8, 2.2 or 5 litres in white HDPE bottles, red polypropylene closure
Packs of 12 or 21 litres in white HDPE bottles, red HDPE closure.

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 if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Do not contaminate ponds, waterways or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4004

9. DATE OF FIRST AUTHORISATION

18 June 1984

10. DATE OF REVISION OF THE TEXT

December 2015

Approved: 15 December 2015