SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 100 10%(w/v) Oral Suspension for Cattle & Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active substance:	
Triclabendazole	10.000% w/v
Excipient(s):	
Antimicrobial preservatives:	
Methyl hydroxybenzoate (E218)	0.110% w/v
Propyl hydroxybenzoate (E216)	0.024% w/v
Benzoic acid (E210)	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

Cattle and Sheep.

4.2 Indications for use, specifying the target species

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

Sheep
For the treatment and control of liver fluke infections in sheep caused by all stages of triclabendazole susceptible *Fasciola hepatica* from 2 day old immature to adult fluke.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

Shake the container thoroughly before use.
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.

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 (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 different mode of action should be used.

Resistance to triclabendazole has been reported in liver fluke (Fasciola hepatica) in cattle and sheep 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. To reduce the risk of parasite resistance, dosing programmes should be discussed with a veterinary surgeon. Fasinex 100 contains the anthelmintic triclabendazole and losses associated with resistant strains of fluke in sheep treated with triclabendazole can be significant. If signs of fasciolosis continue after treatment with Fasinex 100, DO NOT REPEAT THE DOSE and do not dose with other products containing triclabendazole. Seek veterinary advice. If resistance is suspected or confirmed, you should change active ingredient on veterinary advice.

4.5 Special precautions for use

i. Special precautions for use in animals

None.

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

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

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon**.**

4.7 Use during pregnancy, lactation or lay

Cattle
Fasinex is neither embryotoxic nor teratogenic, and can be used in all stages of pregnancy and lactation in cattle not producing milk for human consumption..
Not authorised for use in lactating animals producing milk for human consumption including during the dry period (see 4.11).

Sheep
Fasinex 100 is neither embryotoxic nor teratogenic, and can be used in all stages of pregnancy and lactation in sheep not producing milk for human consumption.
Not authorised for use in ewes 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 Amount(s) to be administered and administration route

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

Routine herd/flock treatment (moderate risk fluke areas)
Dose all animals 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. Animals bought in from fluke risk areas should be treated before joining the main herd/flock.

Clean drenching equipment before and after use.
Use unaltered product from the original container.
Shake the container thoroughly before use.
Most types of automatic drenching gun may be used.

To ensure a correct dosage, body weight 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 over-dosing.

Accuracy of the dosing device should be checked.

Cattle
Administration route:
Fasinex 100 is administered orally.

Administer 3 ml Fasinex 100 per 25 kg body weight, equivalent to 12 mg triclabendazole per kg of body weight.

Dosing Table

Body Weight (kg)	Volume to Administer
Up to 50 kg	6 ml
100 kg	12 ml
150 kg	18 ml
200 kg	24 ml
250 kg	30 ml
300 kg	36 ml
350 kg	42 ml
400 kg	48 ml

For animals over 400 kg, add 3 ml for each additional 25 kg body weight.

Inwintering:
Where cattle are inwintered, a single dose of Fasinex 100 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.

Sheep
Administration route:
FASINEX 100 is administered orally.

Administer 1 ml Fasinex 100 per 10 kg body weight, equivalent to 10 mg triclabendazole per kg of body weight. Always dose to the heaviest member of the group. Fasinex 100 is given once.

Dosing Table

Body Weight (kg)	Volume to Administer
Up to 10 kg	1 ml
11 – 15 kg	1.5 ml
16 - 20 kg	2 ml
21 – 30 kg	3 ml
31 – 40 kg	4 ml
41 - 50 kg	5 ml
51 – 60 kg	6 ml

Add 1 ml for each additional 10 kg body weight.

Treatment of acute outbreaks:
The flock should be treated immediately after diagnosis is reached. 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 body weight (over 12 times the recommended dose for cattle and 15-20 times the recommended dose for sheep) may lead to side effects such as unsteady gait, dullness and reduced appetite. These side effects are slight and transient. An antidote is not known.

4.11 Withdrawal period(s)

Cattle (meat and offal) – 56 days
Sheep (meat and offal) – 35 days
Not authorised in cattle and ewes 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.
Do not use within 1 year prior to the first lambing in ewes 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 and its metabolites bind to tubulin but at another receptor than other benzimidazoles. Triclabendazole and its metabolites interfere with intracellular transport mechanisms and inhibit protein synthesis.

5.2 Pharmacokinetic properties

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. Metabolites are excreted via the bile, primarily as conjugates. More than 90% of the total dose of Fasinex 100 is excreted in the faeces, about 5% in the urine and less than 1% in milk. Elimination is virtually complete by 10 days after administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate (E218)
Propyl hydroxybenzoate (E216)
Benzoic acid (E210)
Polyvinyl pyrrolidone
Microcrystalline cellulose

Croscarmellose sodium
Disodium phosphate dodecahydrate (E339)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf-life after first opening the immediate packaging: 12 months.

6.4 Special precautions for storage

Protect from light. Protect from frost. 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.
Pack of 12 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. The product or empty containers should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4005

9. DATE OF FIRST AUTHORISATION

23 January 2008

10. DATE OF REVISION OF THE TEXT

December 2015

Approved: 15 December 2015