1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240 mg/ml oral suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Triclabendazole 240 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.1 mg
Propyl parahydroxybenzoate (E216)	0.4 mg
Benzyl alcohol (E1519)	5.0 mg
Microcrystalline cellulose and carmellose sodium	
Povidone	
Simethicone Emulsion	
Propylene Glycol	
Purified Water	

White to cream-coloured aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the treatment of acute, subacute and chronic infection due to early immature, immature, and mature stages of *Fasciola hepatica*. If infected animals are treated before disease has developed, fasciolosis can be prevented.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 th=e veterinary medicinal 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 *Fasciola hepatica* in a number of countries including ones in the EU. Therefore, the use of this veterinary medicinal 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. Dosing programmes should be discussed with your Veterinary Adviser.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Only for use for liver fluke strains susceptible to triclabendazole. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce the risk, dosing programs should be discussed with your veterinary practitioner. Efficacy of this veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present. Where a dosing gun is used to administer the veterinary medicinal product, care must be taken to avoid the occurrence of dosing gun pharyngitis.
Not intended for use within 35 days of calving.

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

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

Special precautions for the protection of the environment:

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

Other precautions

None known.

3.6 Adverse events

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy.
Laboratory studies have not produced any evidence of teratogenic or foetotoxic effects.
However, the product is not permitted for use in lactating animals producing milk for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

0.8 L, 2.2 L and 5.0 L pack sizes only:
Unscrew the cap from the container and replace it with the white spigot cap provided. If using an automatic drenching-gun, attach the tube from the application device to the white spigot cap. After use, remove the white spigot cap and close the container with the cap.



All pack sizes:
To ensure a correct dosage, bodyweight 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.
Administer 5 ml/100 kg body weight, equivalent to 12 mg triclabendazole per kg of body weight. The veterinary medicinal product is administered orally after thorough shaking of the suspension. Most types of automatic drenching guns are suitable.
Clean drenching gun before and after use. The veterinary medicinal product can safely be given to young, pregnant or stressed cattle. However, the veterinary medicinal product is not permitted for use in lactating animals producing milk for human consumption.
The veterinary medicinal product is given once. The administration may be repeated several weeks or months after the first treatment depending on the epidemiological situation. In case of sub-acute and acute fasciolosis, affected cattle, usually young animals, should be treated immediately after diagnosis is reached. Advice from your prescriber or veterinary surgeon should be sought for subsequent dosing intervals.

Shake container well before use.

Dosing Table

Body Weight (kg)	Volume to Administer (ml)
Up to 50 kg	2.5
>50-70	3.5
>70-100	5
>100-150	7.5
>150-200	10
>200-300	15
>300-400	20
>400-500	25

Add 5 ml for each additional 100 kg

Dosing recommendations:

On land where sheep are being treated according to a preventative programme and where cattle are also grazing these areas, the veterinary medicinal product should be administered to the cattle on the same treatment dates as the sheep. Use a suitable veterinary medicinal product for use in sheep.

Treatment times should be customised under veterinary advice for each individual farm.

Bought in animals:
All bought in animals should be dosed before joining the main herd unless there is evidence of triclabendazole resistance in those cattle.

Housed cattle:
Dose cattle, which have grazed fluke infected pasture in the autumn at the time of or shortly after housing. Dosing may be required to be started at the beginning of the fluke season when animals are still outdoors depending on the specific farm situation.

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

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

A single oral dose of 150-200 mg triclabendazole/kg of body weight (more than 12 times the recommended dose rate) was shown to lead to side effects such as stumbling gait, depression, and decreased appetite. These side effects are slight and last 1 to 3 days. An antidote is not known.

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: 56 days.

Milk: Not authorised for use in lactating animals producing milk for human consumption.
When used in non-lactating animals, milk for human consumption may only be taken from 48 hours after calving. If calving occurs before 35 days after treatment, milk for human consumption may only be taken after 35 days plus 48 hours after the treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC01

4.2 Pharmacodynamics

Triclabendazole inhibits cellular transport mechanisms and binds to a different tubulin receptor, possibly the tubulozole receptor, than do other benzimidazoles, which bind to the colchicine receptor. Triclabendazole also inhibits protein synthesis.

4.3 Pharmacokinetics

Triclabendazole is readily absorbed and oxidised to its sulfoxide and sulfone.
Triclabendazole sulfoxide reaches peak concentrations approximately 1 day after administration of the veterinary medical product and the sulfone reaches peak concentrations approximately 3 days after administration. Both metabolites bind strongly to plasma protein, particularly albumin.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 12 months.

5.3 Special precautions for storage

Store in the original container.
Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

High density polyethylene bottle (0.8 L, 2.2 L, 5.0 L and 12.0 L).
High density polyethylene induction seal cap. Polypropylene spigot cap (0.8 L, 2.2 L and 5 L). .
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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)

VPA22020/003/001

8. DATE OF FIRST AUTHORISATION

05/09/2008

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

15/07/2026

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).