SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 240 mg/ml Oral Suspension for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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	

Oral Suspension.
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

None known.

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 the 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:

Not applicable.

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:

Not applicable.

Other precautions

None known.

3.6 Adverse events

Target Species: Cattle

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 and lactation.
Laboratory studies have not produced any evidence of teratogenic or foetotoxic effects.
Concerning use during lactation refer to section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

To ensure a correct dosage, 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.

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, cattle not producing milk intended for human consumption or dry cattle.
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 acute fasciolosis, treat immediately, then repeat in approximately 4-6 weeks, and consult a veterinarian for advice.

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

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 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: 52 days.

Milk: Milk for human consumption may only be taken from 48 hours after calving. Not intended for use within 48 days of calving. Should a cow calve earlier than 48 days after the last treatment, milk for human consumption may only be taken from 50 days after the last 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 medicinal 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.
Shake well before use.
Store upright.

5.4 Nature and composition of immediate packaging

High density polyethylene bottles of 0.8, 2.2, 5.0 and 12.0 litres.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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.

The veterinary medicinal product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5102 (GB)
Vm 52127/3037 (NI)

8. DATE OF FIRST AUTHORISATION

05 August 2008

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

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 26 June 2025