SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 24% w/v Oral Suspension for Cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of the product contains:

Active substance:
Triclabendazole 240 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.1 mg
Propyl parahydroxybenzoate (E216)	0.4 mg
Benzyl alcohol (E1519)	5.0 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension.
Cream-coloured aqueous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None known.

4.4 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 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, and 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 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.

4.5 Special precautions for use

(i) Special precautions for use in animals

None known

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

(iii) Other precautions

None known.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy or lactation

FASINEX is neither embryotoxic nor teratogenic, and can be used in all stages of pregnancy. Concerning use during lactation refer to 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

To ensure administration of a correct dose, 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. FASINEX 240 is administered orally after thorough shaking of the suspension. Most types of automatic drenching guns are suitable. Clean drenching gun before and after use. FASINEX can safely be given to young, pregnant or stressed cattle, cattle not producing milk intended for human consumption or dry cattle.
Fasinex 240 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

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

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.

4.11 Withdrawal period

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: triclabendazole is a benzimidazole anthelmintic

ATC Vet code: QP52AC01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Triclabendazole is readily absorbed and oxidised to its sulfoxide and sulfone. Triclabendazole sulfoxide reaches peak concentrations approximately 1 day after administration of FASINEX 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 FASINEX is excreted in the faeces, about 5% in the urine and 1% in milk. Elimination is virtually complete by 10 days after administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Benzyl alcohol (E1519)
Microcrystalline cellulose and carmellose sodium
Povidone
Simethicone Emulsion
Propylene Glycol
Purified Water

6.2 Incompatibilities

None Known

6.3 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

6.4 Special precautions for storage

Store in tightly closed original container. Shake well before use.

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4006

9. DATE OF FIRST AUTHORISATION

05 August 2008

10. DATE OF REVISION OF THE TEXT

September 2020

Approved 09 September 2020