Summary of Product Characteristics

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

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Suspension.
White to 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

Do not use in case of hypersensitivity to the active substance or to any of the ingredients.

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 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 *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
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 product against liver fluke is reduced if triclabendazole resistant strains are present.
Where a dosing gun is used to administer the product, care must be taken to avoid the occurrence of dosing gun pharyngitis.
Not intended for use within 35 days of calving.

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, lactation or lay

Fasinex is neither embryotoxic nor teratogenic, and is safe for use in all stages of pregnancy and lactation. However, the product is not permitted for use in lactating animals producing milk for human consumption.

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 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. However, the product is not permitted for use in lactating animals producing milk for human consumption.
Fasinex 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, Fasinex should be administered to the cattle on the same treatment dates as the sheep. Fasinex 5% should be used 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.

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

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.

4.11 Withdrawal Period(s)

Meat and offal: 56 days.
Milk: 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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: triclabendazole is a benzimidazole anthelmintic
ATCvet 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 properties

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.

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 products or waste materials

Any unused veteinary medicinal product or waste materials derived from such veterinary medicinal product 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

Novartis Animal Health UK Limited
Frimley Business Park
Frimley
Camberley
Surrey GU16 7SR
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10825/004/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th September 2008

Date of last renewal: 24th May 2013

10 DATE OF REVISION OF THE TEXT

February 2014