SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 5% w/v Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	% w/v
Triclabendazole	5.00
Excipients:	
Methyl parahydroxybenzoate	0.11
Propyl parahydroxybenzoate	0.024
Benzoic acid	0.10 as antimicrobial preservatives

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
White to cream-coloured suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

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

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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 body weight, 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* species in small ruminants in a number of countries including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

i. Special precautions for use in animals

Assess bodyweight as accurately as possible before calculating dose. Shake the container thoroughly before use. Clean drenching equipment before and after use. Use unaltered product from the original container.

Parasite resistance to a particular class of anthelmintic may develop following frequent repeated use or misuse of an anthelmintic of that class. 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. If lack of efficacy is suspected seek veterinary advice.

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

When using, do not eat, drink or smoke. Wash splashes from eyes and skin immediately. Take off immediately any contaminated clothing. Wash hands and exposed skin before meals and after work.

4.6 Adverse reactions (frequency and seriousness)

None.

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4.7 Use during pregnancy, lactation or lay

The product can be used in pregnant ewes 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 Amounts to be administered and administration route

For oral administration. Dose: 10mg triclabendazole /kg bodyweight. (1ml Fasinex 5% per 5kg bodyweight).

Do not mix with other products. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Most types of automatic drenching guns may be used.

Do not mix with other products before administration except if premixing is done by a veterinary surgeon or a pharmacist.

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

Routine Flock Treatment (moderate risk fluke areas)
Dose all sheep 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 infestation on pasture in the following autumn.
Any bought in sheep should be treated before joining the main flock.

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

No treatment specified.

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4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 56 days from the last treatment.
Not authorised for use in ewes producing milk for human consumption including during the dry period.
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: Antiparasitic products, insecticides and repellents; Triclabendazole

ATC vet code: QP52AC01

5.1 Pharmacodynamic properties

Triclabendazole is a flukicide.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Benzoic acid
Povidone K30
Cellulose microcrystalline and Sodium croscarmellose (11% Sodium croscarmellose)
Disodium hydrogen phosphate dodecahydrate
Water purified

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 5 years

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6.4 Special precautions for storage

Protect from light. Protect from freezing. Do not store above 25°C.
Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

Packs of 0.8, 2.2 or 5L in white HDPE bottles, blue polypropylene closure.
Packs of 12 or 21L in white HDPE bottles, blue HDPE closure.

Most types of drenching gun can be used.

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

Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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 00879/4007

9. DATE OF FIRST AUTHORISATION

24 January 1984

10. DATE OF REVISION OF THE TEXT

September 2020

Approved 09 September 2020

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