

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclaben 50 mg/ml oral suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Triclabendazole 50 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)	2.0 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Brilliant Blue (E133)	17.5 µg
70% non-crystallising sorbitol, (E420)	-
Polysorbate 80, (E433)	-
Aluminium magnesium silicate	-
Microcrystalline cellulose & carmellose sodium, (E460 and E466)	-
Simethicone emulsion	-
Purified water	-

An aqueous, blue-coloured suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the treatment of fasciolosis in sheep caused by early immature, immature and adult stages of liverfluke (*Fasciola hepatica*) susceptible to triclabendazole.

3.3 Contraindications

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

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.

- Under dosing, which may be due to under estimation of body weight, 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 sheep. Therefore, the use of this veterinary medicinal product should be based on local (regional / farm) epidemiological information about susceptibility of the *Fasciola hepatica* and recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Only use for liverfluke strains susceptible to triclabendazole.

Care must be taken not to damage the mouth or pharyngeal region when dosing. Clean drenching equipment before and after use. Shake container before use. Use unaltered veterinary medicinal product from the original container.

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

When using the veterinary medicinal product do not eat, drink or smoke.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. Wash splashes from eyes and skin immediately. Take off any contaminated clothing immediately. Wash hands and exposed skin before meals and after work. In cases of hypersensitivity and contact allergy, direct skin contact and inhalation should be avoided.

Special precautions for the protection of the environment:

The use of the veterinary medicinal product may have harmful effects on fish and aquatic invertebrates. Sheep must not have any access to surface water such as streams, ponds or ditches within 7 days after treatment with the veterinary medicinal product. When spreading manure from treated animals on arable lands a safety distance of 10 m to adjacent surface waters must be kept.

3.6 Adverse events

Sheep:

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 its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Use properly calibrated dosing equipment.

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.

Recommended dose rate: 10 mg triclabendazole per kg bodyweight as a single administration, i.e., 2 ml per 10 kg body weight.

DOSAGE GUIDE:

Bodyweight	Dosage	Bodyweight	Dosage
Up to 10 kg	2 ml	40 kg	8 ml
15 kg	3 ml	50 kg	10 ml
20 kg	4 ml	60 kg	12 ml
25 kg	5 ml	70 kg	14 ml
30 kg	6 ml	80 kg	16 ml

For animals over 80 kg - give an additional 2 ml for each additional 10 kg bodyweight.

DOSING PROGRAMME:

The timing for treatment should be based on epidemiological factors and should be customized for each individual farm. A dosing programme should be established by the veterinary surgeon.

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

Administration of the veterinary medicinal product is well tolerated in target species when given on a single occasion at 3 times the recommended dose. Following the administration of triclabendazole at 100 mg/kg or more (10 x the recommended dose), reduced appetite, increased blood urea nitrogen and shifts in serum alpha-2-globulin were observed, with a slight increase in absolute liver weight.

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 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP52AC01

4.2 Pharmacodynamics

The veterinary medicinal product contains triclabendazole, a benzimidazole anthelmintic with a narrow spectrum of activity. The precise molecular mode of action of this fasciolicidal drug remains to be elucidated.

4.3 Pharmacokinetics

After oral administration, triclabendazole is rapidly metabolised to its sulfoxide and sulphone metabolites. The sulfoxide is thought to be the active moiety. In sheep the sulfoxide and sulphone metabolites reached a C_{max} of approx. 13 µg/ml and 11 µg/ml at 18 and 30 hours, respectively. The vast majority of oral dose triclabendazole is eliminated in faeces after 7 days. Urinary excretion is minimal.

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.

5.3 Special precautions for storage

Do not store above 25 °C.

Protect from frost.

5.4 Nature and composition of immediate packaging

Container: High density polyethylene

Closure: Copolymer polypropylene with tamper evident seal

Cap Liner: Polyfaced Steran Wad

Spout: Polypropylene

Pack sizes:

1 L pack contains 0.8 L of product or 1 L of product 2.5 L pack contains 2.2 L of product or 2.5L of product 5 L pack contains 5 L of product.

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 or household waste.

The veterinary medicinal product should not enter water courses as triclabendazole may be dangerous for fish and other aquatic organisms.

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

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/058/001

8. DATE OF FIRST AUTHORISATION

06/12/2002

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

16/04/2026

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) (<https://medicines.health.europa.eu/veterinary>).