

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribex 5 % Oral Suspension for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Triclabendazole 50mg

Excipient(s): Each ml contains:

Methyl Parahydroxybenzoate (E218) 2.0 mg

Propyl Parahydroxybenzoate (E216) 0.2 mg

Brilliant Blue (E133) 17.5 microgram

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

An aqueous blue-coloured suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of acute, sub-acute and chronic fasciolosis in sheep caused by early immature, immature and adult stages of liverfluke (*Fasciola hepatica*) susceptible to triclabendazole.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient

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.

- Under dosing, which may be due to under estimation 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 hepatica* in sheep. Therefore, the use of this 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.

4.5 Special precautions for use

Special precautions for use in animals

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 product from the original container.

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

When using the product do not eat, drink or smoke. Wear gloves. 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.

Other precautions

The use of Tribex 5% 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 Tribex. When spreading manure from treated animals on arable lands a safety distance of 10 m to adjacent surface waters must be kept.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

The product can be safely given to pregnant sheep (see section 4.11).

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration only, using properly calibrated dosing equipment. Estimate bodyweight accurately. Shake container before use.

Recommended dose rate: 10 mg triclabendazole per kg bodyweight as a single administration.

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:

Routine treatment (Areas of heavy fluke infection)

As a guide, dose all sheep exposed to fluke infected pastures preventatively at regular intervals of 10 weeks from March/April through to October/November. In situations where stock are out-wintered, another dose in January may be required. All animals grazing the pasture should be treated at these times. All bought in animals should be dosed before joining the main flock. Veterinary advice should be sought with regard to specific preventative dosing regimes.

Routine treatment (Areas of moderate fluke infection)

Dose all sheep on fluke infected pastures at intervals of 10 weeks throughout the fluke season, usually September to January/ February. All bought in animals should be dosed before joining the main flock.

An additional preventative treatment in the spring will assist in reducing the amount of new infestation on pasture in the following autumn.

Treatment of acute outbreaks

The flock should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals. If a preventative fluke dosing programme is employed, the occurrence of acute fluke is greatly reduced. Re-treatment may not be carried out within 8 weeks.

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

No adverse effects were reported following a dose of 12.5 times the recommended dose. At higher doses (up to 20-fold), mild transient ataxia and weight loss were observed in some animals 3-6 days after treatment.

4.11 Withdrawal period(s)

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Benzimidazoles and related substances
ATC vet-code: QP52ACOI

5.1 Pharmacodynamic properties

Triclabendazole differs from other benzimidazoles in that it is a narrow spectrum anthelmintic. The drug accumulates significantly in both immature and adult stages of *Fasciola hepatica* and stimulates the major routes of the parasite's energy generating system, as demonstrated by glucose derived acetate and propionate formation. However, under these conditions the parasite's motility decreased, indicating that the drug is not associated with inhibition of the energy generating pathways. Triclabendazole inhibits colchicine binding to microtubular proteins suggesting interference of the drug with microtubular structure and function. The drug strongly inhibits the release of proteolytic enzymes in immature and adult parasites, a process dependant on microtubular functions. The precise molecular mode of action of this fasciolicidal drug remains to be elucidated.

5.2 Pharmacokinetic particulars

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

70% non-crystallising sorbitol, (E420)
Methyl hydroxybenzoate, (E218)
Propyl hydroxybenzoate, (E216)
Polysorbate 80, (E433)
Aluminium Magnesium silicate
Microcrystalline cellulose & Carmellose sodium, (E460 and E466)
Brilliant blue (E133)
Simethicone emulsion
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from frost.

6.5 Nature and composition of immediate packaging

Pack sizes:
1L pack contains 0.8L of product,
2.5L pack contains 2.2L of product,
5L pack contains 5L of product

Container: High density polyethylene

Closure: Copolymer polypropylene with tamper evident seal

Cap Liner: Polyfaced Steran Wad

Spout: Polypropylene

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/146/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd October 2000

Date of last renewal: 20th June 2007

10 DATE OF REVISION OF THE TEXT

November 2018