1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribex 100 mg/ml Oral Suspension for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Triclabendazole 100 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
Carmoisine supra (EB122).	22.5 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, pink-coloured suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of acute, sub-acute and chronic fasciolosis in cattle caused by early immature, immature and adult stages of liver fluke (Fasciola hepatica) susceptible to triclabendazole.

3.3 Contraindications

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

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 cattle. Therefore, the use of this veterinary medicinal product should be based on local 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 liver fluke strains susceptible to triclabendazole. Frequent and repeated use may lead to the development of resistance. Care must be taken not to damage the mouth or pharyngeal region when dosing. Clean drenching equipment before and after 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 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. Cattle 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

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. The use of suitably calibrated measuring equipment is recommended. To ensure a correct dosage, body weight should be determined as accurately as possible. Shake container before use. Recommended dose rate: 12 mg triclabendazole per kg bodyweight as a single administration.

DOSAGE GUIDE:

Bodyweight	Dosage	Bodyweight	Dosage
Up to 50 kg	6 ml	250 kg	30 ml
100 kg	12 ml	300 kg	36 ml
150 kg	18 ml	350 kg	42 ml
200 kg	24 ml	400 kg	48 ml

For animals over 400 kg - give an additional 6 ml for each additional 50 kg bodyweight.

DOSING PROGRAMME:

Routine treatment (Areas of heavy fluke infection)
As a guide, dose all cattle 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 cattle on fluke infected pastures at intervals of 10 weeks throughout the fluke season, usually September to January/February. An additional preventative treatment in the spring will assist in reducing the amount of new infestation on the pastures in the following autumn. All bought in animals should be dosed before joining the main herd.

In-wintered cattle
Where cattle are in-wintered, a single dose of the veterinary medicinal product should be given 2 weeks after housing.

TREATMENT OF SUB-ACUTE AND ACUTE OUTBREAKS

Affected cattle 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.

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

No adverse effects were reported following a 3-fold overdose in cattle. A single dose of 200 mg/kg causes inappetence, transient weight loss and slight effects on motor activity and serum glucose lactate dehydrogenase (GLDH) in calves.

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 animals producing milk for human consumption.
Non-lactating cattle: Milk for human consumption may only be taken from 84 hours after calving. Not intended for use within 41 days of calving. If calving occurs before 41 days after treatment, milk for human consumption may only be taken after 41 days plus 84 hours after the treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP52ACOI

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

After oral administration, triclabendazole is rapidly metabolised to its sulphoxide and sulphone metabolites. The sulphoxide is thought to be the active moiety. In cattle the sulphoxide and sulphone metabolites reached a Cmax of approx. 13 μg/ml and 26 μg/ml at 18 and 48 hours, respectively. The vast majority of orally administered 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,
2.5 L pack contains 2.2 L of product,
2.5 L pack contains 2.5 L of product,
5 L pack contains 5 L of product
7.5 L pack consisting of 2.5 L & 5 L packs

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)

VPA10987/146/002

8. DATE OF FIRST AUTHORISATION

02/10/2000

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

11/05/2026

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).