Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribex 10 % Oral Suspension for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:		
Triclabendazole	100	mg
Excipients(s):		
Methyl Parahydroxybenzoate (E218)	2.0	mg
Propyl Parahydroxybenzoate (E216)	0.2	mg
Carmoisine supra (EB122).	22.5	microgram

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension
An aqueous pink-coloured suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of acute, sub-acute and chronic fasciolosis in cattle 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 cattle. Therefore, the use of this 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.

4.5 Special precautions for use

Special precautions for use in animals.
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 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 10% 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 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 cattle.

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: 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 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.

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

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.

4.11 Withdrawal period(s)

Meat and offal: 56 days.
Milk:
The product is not permitted for use during lactation in animals producing milk for human consumption. When used in 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.

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 Fasciol 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 cattle the sulphoxide and sulphone metabolites reached a C_{max} of approx. 13 microgram/ml and 26 microgram/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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

70% non-crystallising sorbitol, (E420)
Methyl hydroxybenzoate, (E218)
Propyl hydroxybenzoate,
Polysorbate 80 (E433)
Aluminium Magnesium silicate
Microcrystalline cellulose & carmellose sodium, (E460 and E466)
Carmoisine supra (E122)
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,
2.5L pack contains 2.5L of product,
5L pack contains 5L of product
7.5L pack consisting of 2.5L & 5L packs

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)

VPA10987/146/002

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