Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclaben 10% Oral Suspension for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains	
Active substance:	
Triclabendazole	100mg
Excipient(s):	
Methyl Parahydroxybenzoate (E218)	2.0 mg
Propyl Parahydroxybenzoate (E216)	0.2 mg
Carmoisine supra (E122).	22.5 micrograms

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.
Description: An aqueous pink-coloured suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

Triclaben 10% is indicated for the treatment of 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 liverfluke 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. 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 Triclaben 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 Triclaben. 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)

Occasionally, inflammation of the unpigmented skin, including the udder and the teats, may occur after treatment in cattle exposed to intense sunshine.

4.7 Use during pregnancy, lactation or lay

Triclaben 10% can be used in pregnant cattle.

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 only, using 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: 12 mg triclabendazole per kg bodyweight as a single administration, i.e., 6 ml per 50 kg body weight.

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:
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.
A lasting result, however, can only be expected by involving all potential hosts (domestic ruminants, horse, game animals) in an extensive control programme. The same treatment days should be used for cattle and sheep when a liver fluke dosing programme is implemented and they are grazing the same pasture concurrently; an appropriate authorised product should be used in sheep. All bought in animals, suspected to be infected with liver fluke, should be dosed before joining the main herd.

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

The administration of the product is well tolerated in target species when given on a single occasion at 3 times the recommended dose. A single oral dose of 150-200 mg triclabendazole/kg of live bodyweight may lead to side effects such as unsteady gait, dullness and reduced appetite. These side effects are slight and last 1 to 5 days. An antidote is not known.

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: QP52AC01

5.1 Pharmacodynamic properties

Triclaben 10% 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.

5.2 Pharmacokinetic properties

After oral administration, 50-75% of the dose of triclabendazole is absorbed from the gastrointestinal tract. It is then 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 oral dose triclabendazole is eliminated in faeces after 7 days. Urinary excretion is minimal. Less than 1% is excreted in milk.

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 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 or 1L of product
2.5L pack contains 2.2L of product or 2.5L 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

Triclaben 10% may have toxic effects on fish and aquatic invertebrates. Do not contaminate ponds, waterways or ditches with the product or empty 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

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/059/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 17th April 2008

10 DATE OF REVISION OF THE TEXT

April 2015