Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclaben 5% Oral Suspension for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Each ml contains 50mg Triclabendazole

Adjuvant(s): N/A

Excipient(s): Each ml contains: 2.0mg Methyl Parahydroxybenzoate (E218)
0.2mg Propyl Parahydroxybenzoate (E216)
17.5 microgram Brilliant Blue (E133).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

Triclaben 5% is indicated for the treatment of 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 Triclaben 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 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)

None known.

4.7 Use during pregnancy, lactation or lay

Triclaben 5% can be used in 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.
To ensure administraiton 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 indiviudally, they should be grouped according to their bodyweight and dosed accordingly, in order to avouid under- or over-dosing.

Recommended dose rate: 10 mg triclabendazole per kg bodyweight as a single administration, i.e., 2 ml per 10kg 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	70kg	14 ml
30 kg	6 ml	80kg	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.

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. 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.

4.11 Withdrawal period(s)

Meat and offal: 56 days.
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: QP52AC01

5.1 Pharmacodynamic properties

Triclaben 5% 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 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 oral dose 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 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 derived from the use of such products

Triclaben 5% 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 Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/058/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 December 2002
Date of last renewal: 17 April 2008

10 DATE OF REVISION OF THE TEXT

May 2013