[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclaben 50 mg/ml oral suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Triclabendazole 50 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
Brilliant Blue (E133)	17.5 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, blue-coloured suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the treatment of fasciolosis in sheep caused by early immature, immature and adult stages of liverfluke (*Fasciola hepatica)* susceptible to triclabendazole.

3.3 Contraindications

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

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 sheep. Therefore, the use of this veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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. Sheep 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

Sheep:
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.
Use 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: 10 mg triclabendazole per kg bodyweight as a single administration, i.e., 2 ml per 10 kg 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	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:

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.

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

Administration of the veterinary medicinal 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.

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 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP52AC01

4.2 Pharmacodynamics

The veterinary medicinal product 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.

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 sheep the sulphoxide and sulphone metabolites reached a C_{max} of approx. 13 μg/ml and 11 μg/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.

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 or 1 L of product 2.5 L pack contains 2.2 L of product or 2.5L of product 5 L pack contains 5 L of product.

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)

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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).

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Container Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclaben 50 mg/ml oral suspension for Sheep (IE)
Tribex 50 mg/ml oral suspension for Sheep (FR)
Triclacert 50 mg/ml oral suspension for Sheep (UK)

2. COMPOSITION

Each ml contains

Active substances:
Triclabendazole 50 mg

Excipients:
Methyl parahydroxybenzoate (E218) 2.0 mg
Propyl parahydroxybenzoate (E216) 0.2 mg
Brilliant Blue (E133) 17.5 µg

An aqueous, blue-coloured suspension.

3. PACKAGE SIZE

(0.8 L), (1 L), (2.2 L), (2.5 L), (5 L)

4. TARGET SPECIES

Sheep

5. INDICATIONS FOR USE

Indications for use
For the treatment of fasciolosis in sheep, caused by early immature, immature and adult stages of liver fluke (*Fasciola hepatica*) susceptible to triclabendazole.

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

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 liver fluke (*F hepatica*) in sheep. Therefore, the use of this veterinary medicinal product should be based on local (regional farm) epidemiological information about susceptibility of the liver fluke and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:
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 veterinary medicinal 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. Sheep 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.

Pregnancy:
Can be used during pregnancy.

Overdose:
The administration of the veterinary medicinal 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 (10x 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.

8. ADVERSE EVENTS

Adverse events

Sheep:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details on this label, or via your national reporting system: {national system details}

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
Oral use.
Use properly calibrated dosing equipment.
The recommended dose rate is 10 mg triclabendazole per kg bodyweight as a single administration, which is equivalent to 2.0 ml per 10 kg bodyweight.

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.

Anthelmintics are agents that destroy or result in the expulsion of susceptible parasitic worms. Parasite resistance to a particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.
The veterinary medicinal product contains the anthelmintic triclabendazole. Fluke (*Fasciola hepatica*) resistance to triclabendazole has been identified, and losses associated with resistant strains of fluke in sheep flocks treated with triclabendazole can be significant. If signs of fascioliasis continue after treatment with the veterinary medicinal product, DO NOT REPEAT THE DOSE and do not dose with other products containing triclabendazole. Seek veterinary advice. If resistance is suspected or confirmed, you should change active ingredient on veterinary advice.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. 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.

11. WITHDRAWAL PERIODS

Withdrawal periods
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.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

This product is available in pack sizes of 0.8 L, 1 L, 2.2 L, 2.5 L and 5 L.
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse events>:

Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road
Loughrea
Co. Galway
Ireland
Tel: + 353 91 841788

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

<Other information>

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

21. BATCH NUMBER

Lot {number}