PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribex 50 mg/ml Oral Suspension for Sheep

2. COMPOSITION

Each ml contains:

Active substance:

Triclabendazole, 50 mg/ml

Excipients: 2.0 mg Methyl Parahydroxybenzoate (E218) and 0.2 mg Propyl Parahydroxybenzoate (E216) as preservatives, and brilliant blue (E133).

An aqueous blue-coloured suspension.

3. PACKAGE SIZE

(0.8 L), (2.2 L), (5 L)

4. TARGET SPECIES

Sheep

5. INDICATIONS FOR USE

Indications for use

For the treatment of acute, sub-acute and chronic 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 or to any of the excipients.

7. 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 *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.

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 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:

No adverse effects were reported following a dose of 12.5 times the recommended dose. At higher doses (up to 20-fold), mild transient ataxia and weight loss were observed in some animals 3-6 days after treatment.

8. ADVERSE EVENTS

Adverse events

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 using the contact details on this label, or via your national reporting system at: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine, e-mail: adverse.events@vmd.gov.uk

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

Dosage for each species, routes and method of administration

Oral use.

The recommended dose rate is 10 mg triclabendazole per kg bodyweight as a single administration, which is equivalent to 2.0 ml veterinary medicinal product per 10 kg bodyweight. The veterinary medicinal product can be safely given to pregnant sheep.

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:
Routine treatment (Areas of heavy fluke infection)

As a guide, dose all sheep 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 sheep on fluke infected pastures at intervals of 10 weeks throughout the fluke season, usually September to January/ February. All bought in animals should be dosed before joining the main flock.
An additional preventative treatment in the Spring will assist in reducing the amount of new infestation on pasture in the following Autumn.

Treatment of acute outbreaks
The flock 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. Re-treatment may not be carried out within 8 weeks.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure, a correct dosage 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

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.

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

Vm 08749/5183

Vm 08749/3146

Pack sizes

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

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

17. CONTACT DETAILS

Contact details

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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

18. OTHER INFORMATION

<Other information>

POM-VPS

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 22 July 2026