PARTICULARS TO APPEAR ON THE OUTER PACKAGE {X Litre bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triclacert Duo 50 mg/ml & 1 mg/ml Oral Suspension for Sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Triclabendazole	50 mg
Ivermectin	1 mg

3. PACKAGE SIZE

1 L, 2.5 L, 3 L, 5 L and 10 L.

4. TARGET SPECIES

For sheep over 3 months of age.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use

7. WITHDRAWAL PERIODS

Withdrawal period: Meat and offal: 27 days.
Milk: Not permitted 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 1 year

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C
Store in the original container
Protect from light.
Do not freeze. Protect from frost.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/5202

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Triclacert Duo 50 mg/ml & 1 mg/ml Oral Suspension for Sheep

2. Composition

A smooth white to off white uniform suspension.

Each ml contains:

Active substances:

Triclabendazole	50 mg
Ivermectin	1 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.2 mg
Propyl parahydroxybenzoate	0.5 mg
Benzyl alcohol	27.0 mg

3. Target species

For Sheep over 3 months of age

4. Indications for use

Treatment of mixed trematode (fluke) and nematode or arthropod infections due to gastrointestinal roundworms, lungworms, liver fluke and nasal bots.

Gastrointestinal nematodes (adult and immature):

Haemonchus contortus, Teladorsagia (Ostertagia) circumcincta, Trichostrongylus spp, Cooperia spp, Nematodirus spp including *N. battus*, *Strongyloides papillosus, Oesophagostomum spp*, and adult *Chabertia ovina*.

Inhibited larval stages and benzimidazole resistant strains of *Haemonchus contortus* and *Teladorsagia (Ostertagia) circumcincta* are also controlled.

Liver fluke (mature, immature and early immature stages down to less than 1 week of age): *Fasciola hepatica*

Lungworms (adult and immature): *Dictyocaulus filaria*

Nasal bots (all stages): *Oestrus ovis*

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or any of the excipients.

6. 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.
- Underdosing which may be due to underestimation of bodyweight, 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 ivermectin has been reported in *Teladorsagia (Ostertagia) circumcincta*, *Haemonchus contortus* and *Trichostrongylus* species in sheep, and increasing resistance to triclabendazole has been reported in *Fasciola* species in sheep in a number of countries including in Europe. Therefore, the use of this product should be based upon local (regional, farm) epidemiological information about susceptibility of the target parasites and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:
Extra-label use in dogs should be avoided as severe adverse reactions may occur. In common with other avermectins, certain breeds of dogs, such as Collies, are especially sensitive to ivermectin and particular care should be taken to avoid accidental consumption of the product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

- This product may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to ivermectin, triclabendazole or parabens should avoid contact with the product.
- This product may cause skin and eye irritation.
- Avoid direct contact with the skin and eyes.
- Protective gloves should be worn when handling the product.
- In case of accidental spillage onto skin or into the eyes wash immediately with water. Take off any contaminated clothes.
- Do not eat, drink or smoke whilst handling the product.

- Wash hands and any exposed skin before meals and after work.

Special precautions for the protection of the environment:
Long-term effects on dung insects caused by continuous or repeated use cannot be excluded.
The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of this product and other products of the same anthelmintic class in cattle, sheep and pigs. Therefore, the repetition of treatment in a pasture during a season should be performed only in the absence of alternative treatment and on veterinary advice.

Pregnancy and lactation:
The safety of this veterinary medicinal product has not been established during pregnancy or lactation or in animals intended for breeding. No alteration of lactation has been reported for ivermectin and triclabendazole when used as monotherapy in sheep.

Use only according to the benefit/risk assessment by the responsible veterinarian

Interaction with other medicinal products and other forms of interaction:
No data available

Overdose:
No clinical signs were observed after overdosing 5 times. At 10 times overdosing liver and kidney function may be affected slightly. There is no antidote.

For Animal Treatment only.

7. 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 in this package leaflet, 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, 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

8. Dosage for each species, routes and method of administration

For oral use.

The dose rate is 0.2 mg ivermectin and 10 mg triclabendazole per kg bodyweight equivalent to 2 ml/10 kg bodyweight.

To ensure a correct dosage, bodyweight should be determined as accurately as possible. The product is for oral administration using a suitably calibrated dosing gun. The container should be shaken thoroughly before use. Drenching equipment should be cleaned before and after use.
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 overdosing.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

Dosing Table:

Animal Weight	Dose of the product
20 – 25 kg	5 ml
26 – 30 kg	6 ml
31 – 35 kg	7 ml
36 – 40 kg	8 ml
41 – 50 kg	10 ml
51 – 60 kg	12 ml
61 – 70 kg	14 ml
71 – 80 kg	16 ml
81 – 90 kg	18 ml
91 – 100 kg	20 ml

9. Advice on correct administration

Shake the container thoroughly before use.

Clean drenching equipment before and after use.

10. Withdrawal periods

Meat and offal: 27 days.

Milk: Not permitted 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.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 °C
Store in the original container.
Protect from light.
Do not freeze. 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.
Once opened, use within 1 year. After opening the container for the first time, calculate the discard date which is the opening date plus 1 year. This discard date should be written in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as ivermectin and 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08749/5202

Authorised pack sizes: 1 L, 2.5 L, 3 L, 5 L and 10 L.

Not all pack sizes may be marketed.

15. 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.

16. 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
Telephone: +353 (0)91 841788
e-mail: vetpharmacoviggroup@chanellegroup.ie

Local distributor:
Downland Marketing Ltd.,
Warwick Mill Business Centre,
Warwick Bridge,
Carlisle,
Cumbria CA4 8RR
England

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

17. Other information

POM-VPS

Triclabendazole is persistent in soils.
Ivermectin is highly toxic to aquatic organisms and ivermectin and triclabendazole are highly toxic to dung flies and beetles

Gavin Hall
Approved: 03 November 2025