1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribamec Duo 50 mg/ml + 1 mg/ml Oral Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each ml contains:
Triclabendazole 50.0 mg
Ivermectin 1 mg

Excipients:
Each ml contains:

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)	1.2 mg
Propyl parahydroxybenzoate	0.5 mg
Benzyl alcohol	27.0 mg
Microcrystalline cellulose and Carmellose sodium	
Povidone K30	
Propylene glycol	
Polysorbate 20	
Simethicone Emulsion	
Sodium Dihydrogen Phosphate Monohydrate	
Disodium Phosphate Dihydrate	
Purified water	

A smooth white to off white uniform suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep over 3 months of age.

3.2 Indications for use for each target species

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.

3.3 Contraindications

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the 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.
- 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* in sheep and increasing resistance to triclabendazole has been reported in *Fasciola* species in small ruminants in a number of countries including the EU. Therefore, the use of this product should be based upon local (regional, farm) epidemiological information about susceptibility of the *Teladorsagia (Ostertagia) circumcincta* and trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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

People with known hypersensitivity to the active substances or to the excipients should avoid contact with the product. Direct contact with the skin should be kept to a minimum. Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal 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 exposed skin before meals and after work.

Special precautions for the protection of the environment:

Ivermectin is very toxic to aquatic organisms and dung insects.

3.6 Adverse events

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and Lactation:
The safety of the 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 risk/benefit assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

For oral use. Shake well before 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, body weight 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

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

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.

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: 27 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP 54AA51.

4.2 Pharmacodynamics

Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes and arthropods, followed by paralysis and death.

Triclabendazole interferes with intracellular transport mechanisms and inhibits protein synthesis and is active against the liver fluke Fasciola.

4.3 Pharmacokinetics

Ivermectin is readily absorbed and reaches peak plasma concentrations within 19.7 hours, post administration. Afterwards plasma concentrations decrease with a half-life of 51.4 hours.

Triclabendazole is readily absorbed, oxidised to triclabendazole sulfoxide and to triclabendazole sulfone. Peak plasma concentrations of triclabendazole sulfoxide and triclabendazole sulfone are reached at 20.6 and 36.3 hours, post administration. Afterwards, plasma concentrations decrease with half-lives of triclabendazole sulfoxide and triclabendazole sulfone of 25.5 and 34.8 hours, respectively. Both metabolites bind strongly to plasma proteins, particularly albumin. More than 90% of the dose is excreted in the faeces, about 2% in the urine and less than 1% in the milk within 10 days.

The inter-individual variability of the kinetics of ivermectin and metabolites of triclabendazole in ovine species is high.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 1 year.

5.3 Special precautions for storage

Do not store above 30□C.
Do not refrigerate or freeze.
Protect from frost.
Store in the original container in order to protect from light. Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

The product is available in the following pack sizes:
1 L, 2.5 L, 3 L, 5 L and 10 L.

Container and Closure:
1L, 2.5L, 3L and 5L: White high density polyethylene (HDPE) flexi containers with a polypropylene cap and an aluminium foil seal.
10 L: White HDPE container with a HDPE cap and an aluminium foil seal.

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.

The veterinary medicinal product or used container should not enter water courses as ivermectin may be very 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 Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/167/001

8. DATE OF FIRST AUTHORISATION

20/01/2023

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

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).