SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vimectanin DUO 50 mg/ml + 1 mg/ml oral suspension for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Triclabendazole	50.0 mg
Ivermectin	1.0 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 (E 218)	1.4 mg
Propyl parahydroxybenzoate	0.5 mg
Benzyl alcohol	5.0 mg
Microcrystalline cellulose and carmellose sodium	
Povidone K30	
Propylene glycol	
Disodium phosphate dodecahydrate	
Water, purified	

Homogeneous, white, opaque suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (at least 3 months old)

3.2 Indications for use for each target species

Treatment of simultaneous trematode (fluke) and nematode (gastrointestinal roundworms, lungworms) or trematode (fluke) and arthropod infections in the following cases:

- Gastrointestinal nematodes (adult and immature):

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

- 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 substances or to any of the excipients.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each herd.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture

management measures. Guidance for each specific herd should be sought from the responsible veterinarian.
In the absence of risk of co-infection of nematodes, trematodes and nasal bots, a narrow spectrum product should be used.

In sheep, resistance to ivermectin is widespread in *Teladorsagia circumcincta*, *Trichostrongylus* spp., *Haemonchus contortus* and in other gastro-intestinal parasite species.
Multiple resistance was reported in *Teladorsagia circumcincta* to benzimidazoles, macrocyclic lactones and levamisole and in *Haemonchus contortus* to ivermectin and benzimidazoles.
Resistance to triclabendazole has been reported in *Fasciola hepatica* in sheep.

The use of this product should take into account local information about susceptibility of the target parasites, where available.
It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction test, FECR test). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may cause hypersensitivity (allergic reactions). People with known hypersensitivity to the active substances or to any of the excipients should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may cause skin and eye irritation.
Direct contact with the skin should be kept to a minimum. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
In case of accidental spillage onto skin or into the eyes, wash immediately with plenty of water. Take off any contaminated clothes.
Do not eat, drink or smoke whilst handling the veterinary medicinal product. Wash hands thoroughly after use.

Special precautions for the protection of the environment:
Ivermectin is highly toxic to aquatic organisms, and ivermectin and triclabendazole are highly toxic to dung flies and beetles. 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 repeated treatment of animals on a pasture with an ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

Other precautions:
Extra-label use in dogs should be avoided as severe adverse reactions may occur. Certain breeds of dogs, such as Collies, their related breeds and their mixes are especially sensitive to ivermectin and particular care should be taken to avoid accidental consumption of the product.

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 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

The safety of the veterinary medicinal product has not been established during pregnancy, 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.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

For oral use.

The recommended dose rate is 0.2 mg ivermectin and 10 mg triclabendazole/kg bodyweight, equivalent to 2 ml of the product per 10 kg bodyweight.

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
The product is for oral administration using a suitably calibrated dosing gun. Accuracy of the dosing device should be thoroughly checked. The container should be shaken for 1 minute before use. Drenching equipment should be cleaned before and after use.

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.

For infections with parasites listed at the indications, the need for and frequency of re-treatment(s) should be beased on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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 known 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 animals 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. PHARMACOLOGICA INFORMATION

4.1 ATCvet code: QP54AA51

4.2 Pharmacodynamics

Avermectins, interact with glutamate-gated chloride ion channels, to increase the chloride ion permeability of the cell membrane, causing irreversible neuromuscular blockade in nematodes and arthropods, leading to paralysis and death of parasites.
In nematodes, extensive research has indicated that common mechanisms of resistance against ivermectin include GluCl mutations, changes to ABC transporter expression, and through upregulation of detoxification genes. In arthropods in general, target-site resistance is a common mechanism of insecticide resistance. Selection of resistant isolates with ivermectin leads to cross-resistance to eprinomectin and moxidectin depending upon the underlying mechanism of resistance.
Triclabendazole interferes with the intracellular transport mechanism of cells and inhibits protein synthesis. It is effective against liver fluke *Fasciola*.
Possible mechanism(s) of resistance to triclabendazole that have been studied are: tubulin binding, altered drug uptake and modified drug metabolism, but the molecular basis for each of these possibilities has yet to be identified. So, it is likely that drug resistance in *F. hepatica* is polygenic in nature.

4.3 Pharmacokinetics

Ivermectin is rapidly absorbed and reaches peak plasma concentration within 1 day. Afterwards plasma concentrations decrease with a half-life of 3.5 days.
Triclabendazole is rapidly absorbed, oxidised to triclabendazole sulfoxide and triclabendazole sulfone. Peak plasma concentration is reached within 12 hours.

Afterwards plasma concentration decreases, with a half-life of 16 hours. Both metabolites bind strongly to plasma proteins, particularly albumin. More than 90% of the dose is excreted in the faeces, 2% in the urine and less than 1% in 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: 2 years.
Shelf life after first opening the immediate packaging: 18 months.

5.3 Special precautions for storage

Store in the original package
Do not refrigerate. Protect from frost.

5.4 Nature and composition of immediate packaging

1 litre high density polyethylene back pack with tamper evident polypropylene cap
5 litre high density polyethylene back pack with tamper evident polypropylene cap

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 ivermectin is dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or used container.
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

Pharma VIM Kft.

7. MARKETING AUTHORISATION NUMBER

Vm 59599/3000

8. DATE OF FIRST AUTHORISATION

31 October 2024

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

February 2026

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).

Gavin Hall
Approved: 22 February 2026