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

1 L HDPE bottle and 5 L HDPE can

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Active substances:

Triclabendazole	50.0 mg
Ivermectin	1.0 mg

Excipients:

Methyl parahydroxybenzoate (E 218)	1.4 mg/ml
Propyl parahydroxybenzoate	0.5 mg/ml
Benzyl alcohol	5.0 mg/ml

Homogeneous, white, opaque suspension

3. PACKAGE SIZE

1 L
5 L

4. TARGET SPECIES

Sheep (at least 3 months old)

5. INDICATIONS FOR USE

Indications for use

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

6. CONTRAINDICATIONS

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

7. SPECIAL WARNINGS

Special warnings

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.

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.

Pregnancy and lactation:
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.

Interactions 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 known antidote.

Special restrictions for use and special conditions for use:
Not applicable.

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

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.

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

Dosage for each species, routes and method of administration
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.

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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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.

11. WITHDRAWAL PERIODS

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.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label. 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 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 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 NUMBER AND PACK SIZES

Vm 59599/3000

Pack sizes

1 litre high density polyethylene bottle with high density polyethylene cap with safety seal
5 litre high density polyethylene can with high density polyethylene cap with safety seal
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:
Pharma VIM Kft.
Pipiter Utca 5
Budapest II
1029
Hungary

Manufacturer responsible for batch release:
Vim Spectrum SRL, 547367 Corunca, no. 409, Romania

18. OTHER INFORMATION

Other information
None.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 18 months.

21. BATCH NUMBER

Lot {number}

EAN barcode, GTIN-13

Gavin Hall
Approved: 20 December 2024