

COMBINED LABEL AND PACKAGE LEAFLET

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

{plastic bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OVIVERM 25 mg/ml Oral Suspension for Sheep

2. COMPOSITION

Each ml contains:

Active substance(s):

Praziquantel 25 mg

Excipients:

Sodium propionate (E 281) 2 mg

Sodium benzoate (E 211) 2 mg

A white suspension.

3. PACKAGE SIZE

1 x 950 ml

4. TARGET SPECIES

Sheep.



5. INDICATIONS FOR USE

Indications for use

For the treatment of tapeworm infestations with adult intestinal stages of *Moniezia* spp.

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

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 infestation based on its epidemiological features, for each flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole flock 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 flock should be sought from the responsible veterinarian.

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

This product contains propylene glycol, polysorbate, and sodium benzoate, which may cause allergic reactions in sensitised people.

This product may cause irritation of the eyes and skin after contact. Avoid skin and eye contact with the product and rinse any splashes off immediately with water.

If you develop symptoms of allergy, or if irritation persists, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy:

Can be used during pregnancy.

Laboratory studies in sheep have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects, or toxic effects for newborn lambs.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

No adverse effects were noted after administration of 5-times the recommended dosage of praziquantel.

Major incompatibilities:

None known.

8. ADVERSE EVENTS

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 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 or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

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

Dosage for each species, routes and method of administration

Single oral use.
The dose is 3.75 mg of praziquantel per kg of body weight. This equals to 3 ml of suspension per 20 kg of body weight.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Shake well before use.

Administration is performed using an automatic oral applicator (drencher), which allows simple and safe administration of the suspension. Adjust the opening in the neck of the bottle for a convenient connection of the tube to the drencher.

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. Accuracy of the dosing device should be thoroughly checked.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: Zero days.
Milk: Zero hours.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 46608/3004

Pack sizes

1 x 950 ml

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:

Bioveta, a.s.
Komenského 212/12
Ivanovice na Hané
683 23
Czech Republic



Tel.: +420 517 318 911
E-mail: reklamace@bioveta.cz

Local representative

Animal Health Distributors
Industrial Estate
Tullow
Co. Carlow
Tel.: 00 353 59 915 1251
Email: Pharmacovigilance@animalhealthdistributors.ie

<Contact details to report suspected adverse reactions>:>

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

18. OTHER INFORMATION

Environmental properties:
Praziquantel is toxic to dung organisms.

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: 10 weeks.

21. BATCH NUMBER

Lot {number}

Approved 02 December 2025
Gavin Hall