

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OVIVERM 25 mg/ml Oral Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance(s):

Praziquantel 25 mg

Excipients:

Qualitative composition of excipients and other constituents:	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium propionate (E 281)	2 mg
Sodium benzoate (E 211)	2 mg
Sorbitan oleate	
Polysorbate 80	
Bentonite	
Citric acid monohydrate	
Xanthan gum	
Propylene glycol	
Purified water	

A white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

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:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep:
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:

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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Single oral use.

Shake well before 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.

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.

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

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

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: Zero days.

Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AA01

4.2 Pharmacodynamics

Praziquantel, a partially hydrogenated pyrazinoisocholine derivative, is an anthelmintic.

The spectrum of praziquantel efficacy includes all common *Moniezia* species in sheep. Praziquantel acts against the mature developmental stages of these parasites occurring in the gut of sheep. Praziquantel is very rapidly resorbed through the surface of the parasite's body and evenly distributed in the parasite. Severe damage to the parasite's integument occurs very rapidly *in vitro* and *in vivo*, resulting in contraction and paralysis of the parasite. The basis for this rapid onset of action is the change in Ca²⁺ permeability of the parasite's membranes triggered by praziquantel and the resulting disruption of the parasite's metabolism.

4.3 Pharmacokinetics

Praziquantel is absorbed very rapidly and almost completely in the stomach and small intestine following oral administration in sheep. Maximum serum levels are reached within 0.3-2 hours. Praziquantel is rapidly distributed into all organs. The elimination half-life of ¹⁴C-praziquantel and its metabolites is 2-3 hours in sheep. Praziquantel is rapidly metabolised in the liver. Among other metabolites, the main metabolite occurring is the 4-hydroxycyclohexyl derivative of praziquantel. Praziquantel is completely eliminated from the body within 48 hours in the form of its metabolites, from 40% to 71% in the urine and bile, from 13% to 30 % in the faeces.

Environmental properties

Praziquantel is toxic to dung organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 10 weeks.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

950 ml of the veterinary medicinal product in a 1000 ml plastic bottle (PET) with a reduction (LDPE) in the neck and with a screw cap with protection of originality (PP and HDPE).

Each bottle is labelled with the text of package leaflet.

Pack size: 1 x 950 ml

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.

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

Bioveta, a.s.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22028/007/001

8. DATE OF FIRST AUTHORISATION

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>).