SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Supaverm Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

50 mg closantel (as closantel sodium dihydrate)
75 mg mebendazole

Excipients:

Qualitative composition of excipients and other constituents
Propylene Glycol
Cellulose Microcrystalline and Croscarmellose Sodium
Hypromellose
Sodium Laurilulfate
Simethicone Emulsion 30 %
Water Purified

White to faintly cream coloured suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and lambs.

3.2 Indications for use for each target species

For the control of fascioliasis (due to *Fasciola hepatica*) and gastrointestinal nematodes and cestodes in sheep and lambs. The combination is active against lungworm, roundworms, tapeworms (heads and segments) and fluke (mature and immature).

For the control of the larval stages of *Oestrus ovis* (Sheep Nasal Bot fly).

For the control of inhibited, immature and adult stages of *Haemonchus contortus* (Barber Pole worm) including benzimidazole resistant strains.

Also effective against benzimidazole susceptible strains of the following:

Gastro-intestinal roundworms: *Ostertagia* spp, *Trichostrongylus* spp, *Nematodirus* spp, *Cooperia* spp, *Oesophagostomum* spp, *Chabertia ovina, Bunostomum* spp, *Trichurus ovis*, *Strongyloides papillosus*.
Lungworm: *Dictyocaulus filaria*
Tapeworm: *Moniezia* spp.

Fluke activity:

Stage	*Percentage kill*
Adults	97-100 %
6-8 weeks immature	91-95 %
5 weeks immature	91 %
3-4 weeks immature	23-73 %

Ticks (*Ixodes ricinus*) feeding on sheep at the time of treatment are likely to produce fewer viable eggs.

3.3 Contraindications

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

3.4 Special warnings

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 body weight, 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 benzimidazoles (which includes mebendazole) has been reported in *Teladorsagia, Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries including the EU. Resistance to closantel has been reported in *Haemonchus* in sheep outside the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics
To reduce the risk of anthelmintic resistance, dosing programmes should be discussed with a veterinary surgeon.

3.5 Special precautions for use

Special precautions for safe use in the target species:

As overdosage may result in signs of toxicity such as incoordination and blindness, care should be taken to ensure animals are not overdosed by volume. If the product is spilled, care should be taken to ensure animals do not ingest it.

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

This product may be irritating to skin and eyes and users should be careful not to accidentally splash it on themselves or others. Wear impermeable rubber gloves when applying the product. Remove any contaminated clothing immediately.
In case of accidental spillage onto skin or into eyes, rinse the affected area with large amounts of clean water. If irritation persists, seek medical advice immediately and show the package leaflet or label to the physician.
This product may be toxic after accidental ingestion. Avoid ingestion by hand-to-mouth contact. Do not eat, drink or smoke whilst handling the product. If accidental ingestion occurs, seek medical attention and show the package leaflet or label to the physician. Wash hands after use.

Special precautions for the protection of the environment:

This product is toxic to aquatic organisms and dung insects. Long-term effects on dung insects caused by continuous or repeated use cannot be excluded. Repeat treatments on a pasture within a season should only be given on the advice of the prescriber. To reduce the risk for dung fauna, if the worming protocol allows, treated and untreated animals should be grazed on the same field. The risk to aquatic ecosystems will be reduced by keeping treated animals away from water bodies for 48 hours after treatment.

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

Pregnancy and lactation:
May be administered to pregnant animals.
The product may be used during the lactation period but not where milk is used for human consumption. See section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral administration as a drench.
Suitable for use with most types of standard drenching equipment.
1 ml per 5 kg bodyweight (ie 10 mg/kg bodyweight closantel and 15 mg/kg bodyweight mebendazole).

For example:

Bodyweight	*Dose*
Up to 5 kg	1 ml
6-10 kg	2 ml
11-20 kg	4 ml
21-30 kg	6 ml
31-40 kg	8 ml
41-50 kg	10 ml
51-60 kg	12 ml
61-70 kg	14 ml
71-80 kg	16 ml

To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Shake container well before each use. Do not mix with other products.

Gastrointestinal worms

The frequency of treatment will depend on the level of pasture contamination. A suggested programme is to treat ewes prior to lambing, 6 weeks after lambing and prior to tupping to reduce pasture contamination. Dose lambs at regular intervals during high-risk periods. Rams may be treated at any time as necessary.

H. contortus

For the treatment and prevention of inhibited, immature and adult stages of benzimidazole resistant and susceptible *H. contortus*, dose at lambing to help prevent pasture contamination by infected ewes. Treat all animals at 6 weekly intervals during high-risk periods in summer and autumn.

Fluke

All sheep on infested pasture should be dosed at regular intervals during the fluke season (Sept-Mar).

Since closantel has been shown to delay egg-laying for up to 13 weeks after artificial infection, treatment intervals of 10-12 weeks throughout the fluke season are recommended. In severe fluke seasons, more frequent dosing may be necessary.

The treatment of ewes with a single dose in the spring will contribute to reducing pasture contamination during the following summer and autumn.

Any sheep brought in from fluke areas should be dosed before they join the flock.

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

Symptoms of serious closantel overdosage are decreased vision or blindness, anorexia, in-coordination and general weakness.

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: 65 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: QP52A

The veterinary medicinal product is a combination of the salicylanilide closantel and the benzimidazole mebendazole. Closantel is highly effective against liver flukes and haematophagous nematodes in sheep and goats and against larval stages of some arthropods in sheep. Mebendazole is highly active against gastrointestinal nematodes in sheep and goats and against lungworms and cestodes in sheep.

Closantel is an uncoupler of the mitochondrial oxidative phosphorylation resulting in inhibition of the ATP-synthesis. This induces a dramatic change in the energy metabolism which finally leads to the death of the parasite.

Mebendazole has a selective anthelmintic action through a specific interaction with the microtubular system of the absorptive cells of the parasite, leading to an irreversible lytic destruction of these cells and death of the worm.

Environmental properties

Closantel has the potential to adversely affect non-target organisms. Following

treatment, excretion of potentially toxic levels of closantel may occur over a period of several weeks. Faeces containing closantel excreted onto pasture from treated animals may reduce the abundance of dung feeding organisms which may impact dung degradation in the field.

5. PHARMACEUTICAL PARTICULARS

Closantel is rapidly absorbed into the systemic circulation after oral administration and peak plasma levels are attained at 24-48 hours after dosing. In plasma, closantel is bound more than 99 % to albumin. As a result, tissue distribution is very limited. On average, tissue levels are 15 times lower than plasma levels. The elimination half-life from plasma and tissues is 2 to 3 weeks in sheep and about 10 days in goats. Metabolism is negligible and the main excretion route is the bile. The urinary excretion is negligible.

Mebendazole is of low solubility and only slightly absorbed from the gastrointestinal tract. Consequently, mebendazole is eliminated almost unaltered via the faeces after oral administration of therapeutic doses. The slight fraction that is absorbed produces maximal plasma levels within 24 hours of administration. The absorbed fraction is metabolised by the liver. The metabolites are mainly eliminated via urine. Seven days after treatment, tissue levels of mebendazole are below the detection limit.

The kinetics of both active ingredients are not altered when given in the combination.

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Protect from light.
Keep container in outer carton.

5.4 Nature and composition of immediate packaging

1, 2.5, and 5 litre high-density polyethylene flexitainers with HDPE tamper evident caps and nozzles
9 and 10 litre high-density polyethylene jerrycans with white HDPE polyethylene cap with aluminium (triseal) insert or ureum cap with HDPE polyethylene insert.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.
The veterinary medicinal product should not enter water courses as closantel may be 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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5082

8. DATE OF FIRST AUTHORISATION

11 April 1988

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

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 23 April 2026