Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Supaverm Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substances:
Closantel (as Closantel Sodium Dihydrate) 50 mg
Mebendazole 75 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep and lambs.

4.2 Indications for use, specifying the target species

For the treatment and control of liver fluke, gastro-intestinal nematodes, lungworms, cestodes and larval stages of some arthropods.

Trematodes:
Liver flukes:
Fasciola hepatica (adults + 5-8 week immatures)
Fasciola gigantica (adults + 8 week immatures)

Nematodes:
Roundworms:
Haemonchus contortus (adults, immatures, inhibited stages and BZ-resistant strains)
Bunostomum spp. (adult)
Chabertia ovina (adults + immatures)
Gaigeria pachyscelis (adults + immatures)
Oesophagostomum spp. (adults)
Capillaria spp. (adults)
Cooperia spp. (adults)
Nematodirus spp. (adults + immatures)
Ostertagia circumcinta (adults + immatures)
Trichostrongylus axei (adults)
Trichostrongylus colubriformis (adults + immatures)
Trichostrongylus vitrinus (adults)
Trichuris ovis (adults)
Strongyloides papillosus (adults + immature)

Lungworms:
Dictyocaulus filaria (adults + immatures)

Cestodes:
Avitellina spp.
Moniezia spp.

Arthropods:
Oestrus ovis (nasal bot) 1st, 2nd and 3rd instar.
Ticks (*Ixodes ricinus*) feeding on sheep at the time of treatment are likely to produce fewer viable eggs.

4.3 Contraindications

Do not administer to animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals:
Supaverm is to be administered carefully with a drenching gun. Care must be taken to avoid causing injury to the mouth or pharynx during dosing.
Do not exceed the stated dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash splashes from eyes and skin immediately.
Take off immediately any contaminated clothing.
Wash hands and exposed skin before meals and after work.

4.6 Adverse reactions (frequency and seriousness)

At therapeutic doses, Supaverm is not toxic and causes no side-effects.

4.7 Use during pregnancy, lactation or lay

Supaverm can be used at any time during pregnancy and during the lactating period. See section 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration.
Bodyweight of animals should be assessed accurately.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.
Do not exceed the stated dose of Supaverm.

Shake well before use. Invert at least 10 times before use.The recommended dose is 10 mg/kg BW closantel + 15 mg/kg BW mebendazole. This corresponds to 1 ml per 5 kg BW.
Supaverm is to be administered by means of a drenching gun.

All sheep on infested pasture should be dosed at regular intervals during the fluke season. The interval between dosing will depend on the level of pasture contamination; in severe fluke seasons, dosing every 6-8 weeks may be necessary. Supaverm is active against worm eggs and prevents pasture contamination with fluke eggs for approximately 13 weeks. Treatment intervals of 10-12 weeks throughout the fluke season are recommended.

Because of its long half-life, closantel will protect for several weeks against reinfections with the following species in sheep:

Residual activity	**Dose (mg/kg)**	**Protection Period**
Haemonchus contortus	10	7 weeks
Oesophagostomum columbianum	10	2 weeks
Gaigeria pachyscelis	10	8 weeks
Oestrus ovis	10	8 weeks

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both fluke- and roundworm infestations.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Symptoms of acute closantel overdosage are decreased vision or blindness, anorexia, inco-ordination and general weakness.

4.11 Withdrawal period(s)

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, combinations of benzimidazoles and related substances. ATCvet Code: QP52AC30

5.1 Pharmacodynamic properties

Supaverm is a combination of the salicylanilide closantel and the benzimidazole mebendazole. Closantel is highly effective against liver flukes, haematophagous nematodes and larval stages of some arthropods. Mebendazole is highly active against gastro-intestinal nematodes, lungworms and cestodes.

Mode of action:
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, leading to an irreversible lytic destruction and death of the worm.

5.2 Pharmacokinetic 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 for 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. Metabolism is absent and the main excretion route is the bile. The urinary excretion is negligible.

Mebendazole is poorly soluble in aqueous systems, which results in a low dissolution rate and a low absorption. This is reflected by the high faecal excretion of unchanged parent drug. The very small fraction absorbed is almost completely metabolised by first pass metabolism in the liver, which consists of carbamate hydrolysis and ketone reduction. The degradation products are conjugated to glucuronides and excreted with the bile and urine. The urinary excretion is relatively poor and consists almost exclusively of metabolites. The kinetics of the active ingredients are not altered when used in combination.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Microcrystalline cellulose and carmellose sodium
Hypromellose
Sodium Laurilsulfate
Simethicone emulsion 30%
Purified Water
Citric Acid 0.5% solution (for pH adjustment)
Sodium Hydroxide 1N solution (for pH adjustment)

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Container: Polyethylene bottles of 1, 2.5, 5, 10 and 20 litres containing a white suspension.
Closure: Ureum screw cap with HDPE insert.
Not all pack sizes may be marketed.

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

Do not contaminate ponds, waterways or ditches with product or used containers.
Dispose of used containers safely.
Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

July 2018