SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Supaverm Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

	% w/v
Closantel (as closantel sodium dihydrate)	5
Mebendazole	7.5

Excipients:
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension
White to faintly cream coloured suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and lambs.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for 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 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.

4.5 Special precautions for use

i. Special precautions for use in animals

None

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

Wash hands after administration. Wash splashes from skin and eyes immediately. Take off any contaminated clothing. Wash hands and exposed skin before meals and after work.

4.6 Adverse reactions (frequency and seriousness)

At therapeutic doses, the combination is not toxic and causes no side effects.

4.7 Use during pregnancy, lactation or lay

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 4.11

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

Give orally as a drench by careful administration with a drenching gun. Suitable for use with most types of standard drenching equipment. To ensure administration of a correct dose, 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.

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

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

4.11 WITHDRAWAL PERIOD(S)

Sheep (Meat): 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 PROPERTIES

5.1 Pharmacodynamic properties

ATC Vet Code: QP52A

Pharmacotherapeutic group: Anthelmintics, Quinoline derivatives and related substances

Supaverm 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.

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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Cellulose Microcrystalline and Croscarmellose Sodium
Hypromellose
Sodium Lauryl Sulphate
Simethicone Emulsion 30 %
Water Purified

6.2 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

Protect from light.

6.5 Nature and composition of immediate packaging

Supaverm is packed in white, high-density flexitainers with HDPE tamper evident caps and nozzles containing 1, 2.5, and 5 litres of product; or 9 and 10 litres in 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

Eli Lilly and Company Ltd
Elanco Animal Health
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00006/4143

9. DATE OF FIRST AUTHORISATION

Date: 11th April 1988

10. DATE OF REVISION OF THE TEXT

Date: June 2013

APPROVED T. NASH **20/06/13**