ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Supaverm Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of oral suspension contains 50 mg closantel and 75 mg mebendazole.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

1 Litre
2.5 Litres
5 Litres

5. TARGET SPECIES

Sheep and lambs
<pictogram of sheep head)

6. INDICATION(S)

Effective against mature and immature fluke, gastrointestinal roundworms and tapeworms (heads and segments), lungworm, inhibited, immature and adult stages of *Haemonchus contortus*, including benzimidazole resistant strains, and larval stages of *Oestrus ovis* (nasal bot fly).
Ticks (*Ixodes ricinus*) feeding on sheep at the time of treatment are likely to produce fewer viable eggs.

FLUKE ACTIVITY

Stage	% KILL
Adults	97-100 %
6-8 weeks immature	91-95 %
5 weeks immature	91 %
3-4 weeks immature	23-73 %
Prevents pasture contamination for up to 13 weeks after dosing.	

Fluke and worm combination oral suspension.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml of Supaverm per 5 kg bodyweight (ie 10 mg/kg closantel and 15 mg/kg mebendazole).
For example:

1 Litre

Bodyweight	Dose	No. of doses per pack
Up to 5 kg	1 ml	1000
6-10 kg	2 ml	500
11-20 kg	4 ml	250
21-30 kg	6 ml	166
31-40 kg	8 ml	125
41-50 kg	10 ml	100
51-60 kg	12 ml	83
61-70 kg	14 ml	71
71-80 kg	16 ml	62

2.5 Litres

Bodyweight	Dose	No. of doses per pack
Up to 5 kg	1 ml	2500
6-10 kg	2 ml	1250
11-20 kg	4 ml	625
21-30 kg	6 ml	416
31-40 kg	8 ml	312
41-50 kg	10 ml	250
51-60 kg	12 ml	208
61-70 kg	14 ml	178
71-80 kg	16 ml	156

5 Litres

Bodyweight	Dose	No. of doses per pack
Up to 5 kg	1 ml	5000
6-10 kg	2 ml	2500
11-20 kg	4 ml	1250
21-30 kg	6 ml	833
31-40 kg	8 ml	625
41-50 kg	10 ml	500
51-60 kg	12 ml	416
61-70 kg	14 ml	357
71-80 kg	16 ml	312

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, bodyweight 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.

SUGGESTED DOSING SCHEDULE:

Gastro-intestinal Worms

The frequency of treatment with Supaverm will depend on the level of pasture contamination. 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.

Haemonchus contortus

For the treatment and prevention of inhibited, immature and adult stages of benzimidazole resistant and susceptible *Haemonchus contortus*, dose at lambing to 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 of Supaverm 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.

Use with automatic drenching equipment:

1. Shake bottle and hold upright.
2. Clip the strap to one of the holes at the base of the bottle and attach the other end to the appropriate hole at the top. This will allow the bottle to hang comfortably.
3. Remove the cap and replace with nozzle provided.
4. Attach the tube leading from the drenching equipment firmly to the nozzle.
5. Hang the bottle upside down and gently prime the gun ready for use.
6. If the contents are not entirely used, the plain cap must be replaced to protect the contents for further use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

(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.

9. SPECIAL WARNING(S), IF NECESSARY

In Animals: At therapeutic doses, the combination is not toxic and causes no side effects. Do not exceed stated dose. Assess bodyweight as accurately as possible before calculating dose. Avoid injury to mouth and pharynx during drenching.

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.

Overdose: Symptoms of serious closantel overdosage are decreased vision or blindness, loss of appetite, lack of coordination and general weakness.

Special precautions for use in animals:
Care should be taken to ensure animals are not overdosed by the administered volume or accidental spillage, as overdosage may result in signs of toxicity such as incoordination and blindness.
User warnings:
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.

Other precautions:
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.

PREGNANCY AND LACTATION Product may be administered during pregnancy. May be used during lactation, but not where milk is used for human consumption. See Withdrawal Periods.

10. EXPIRY DATE

Use by end: {month/year}>

11. SPECIAL STORAGE CONDITIONS

Protect from light. Keep container in outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.
DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY
Legal category: POM-VPS

To be supplied only on veterinary prescription.
UK Authorised Veterinary Medicinal Product

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4181

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

18. OTHER INFORMATION

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.

Chemical group of anthelmintic | 1-BZ |

Manufactured by:
Lusomedicamenta, Sociedade Técnica Farmacêutica S.A.,
Estrada Consiglieri Pedroso, n.° 66, 69-B
Queluz de Baixo, 2730-055
Barcarena, Portugal

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Front + back container labels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Supaverm Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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75 mg mebendazole

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DOSAGE AND ADMINISTRATION
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User warnings: 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.

Other precautions:
Long-term effects on dung insects caused by continuous or repeated use cannot be excluded. Repeat use should be discussed with your prescriber and based on the clinical need of the animal. Ensure unused product is disposed of in line with local regulations and not poured onto land or allowed to enter watercourses.

PREGNANCY AND LACTATION Product may be administered during pregnancy. May be used during lactation, but not where milk is used for human consumption. See Withdrawal Periods.

10. EXPIRY DATE

Use by end: {month/year}

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Estrada Consiglieri Pedroso, n.° 66, 69-B
Queluz de Baixo, 2730-055
Barcarena, Portugal

Approved 22 March 2023