

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mebadown Super 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

6. INDICATION(S)

Effective against roundworms, including inhibited, immature and adult stages and benzimidazole resistant strains of *Haemonchus contortus*, lungworm, tapeworms (heads and segments) and fluke (mature and immature *Fasciola hepatica*). Also effective against nasal bot fly (*Oestrus ovis*).
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.	

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml of Mebadown Super 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

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.

SUGGESTED DOSING SCHEDULE:

Gastro-intestinal Worms

The frequency of treatment with Mebadown Super 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 infected 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 Mebadown Super 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. 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.

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.

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. The time between withdrawal of the first and last doses from the container should not be unduly prolonged.

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

Eli Lilly and Company Limited,
Elanco Animal Health,
Priestley Road,
Basingstoke, Hampshire,
RG24 9NL, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00006/4144

17. MANUFACTURER’S BATCH NUMBER

Batch No: {number}

OTHER INFORMATION

Chemical group of anthelmintic 1-BZ

Manufactured by:
Lusomedicamenta Sociedade Técnica Farmacêutica S.A.
Estrada Consiglieri Pedroso 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

Mebadown Super Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of oral suspension contains:

50 mg closantel

75 mg mebendazole

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

1 Litre

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5 Litres

5. TARGET SPECIES

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DOSAGE AND ADMINISTRATION

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1 Litre

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Give orally as a drench

Suitable for use with most types of standard 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.

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Approved: 03/05/2017

