ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukiver 5% w/v Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Drench containing 50 mg/ml closantel (as closantel sodium)
Each ml contains: 50 mg closantel (as closantel sodium)

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)

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.	

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION
1 ml of Flukiver per 5 kg bodyweight (ie 10 mg closantel per kg bodyweight)

1 Litre pack

Bodyweight	Dose	No. Doses per Pack
5 kg	1 ml	1000
10 kg	2 ml	500
20 kg	4 ml	250
30 kg	6 ml	166
40 kg	8 ml	125
50 kg	10 ml	100
60 kg	12 ml	83
70 kg	14 ml	71
80 kg	16 ml	62

2.5 Litres pack

Bodyweight	Dose	No. Doses per Pack
5 kg	1 ml	2,500
10 kg	2 ml	1,250
20 kg	4 ml	625
30 kg	6 ml	416
40 kg	8 ml	312
50 kg	10 ml	250
60 kg	12 ml	208
70 kg	14 ml	178
80 kg	16 ml	156

5 Litres pack

Bodyweight	Dose	No. Doses per Pack
5 kg	1 ml	5,000
10 kg	2 ml	2,500
20 kg	4 ml	1,250
30 kg	6 ml	832
40 kg	8 ml	624
50 kg	10 ml	500
60 kg	12 ml	416
70 kg	14 ml	357
80 kg	16 ml	312

Use orally as a drench using 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 WELL BEFORE USE
Do not mix with other products.

USE WITH AUTOMATIC DRENCHING EQUIPMENT

1. Shake bottle and hold upright.
2. Thread the strap through one of the holes at the base of the bottle and attach at the appropriate hole at the top of the bottle, to 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.

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

8. WITHDRAWAL PERIOD(S)

WITHDRAWAL PERIOD (meat): 42 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

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 closantel has been reported in *Haemonchus* in sheep outside the EU.
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.

SPECIAL WARNINGS

In Animals: Do not exceed the stated dose. Avoid injury to mouth and pharynx during drenching.
Overdose: Symptoms of acute overdosage are decreased vision or blindness, anorexia, in-coordination and general weakness.
Person Administering the Product: Wash hands after use.

10. EXPIRY DATE

Use by end: {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Do not store above 25 °C. Protect from light.
The time between taking the first and last doses from the container should not be too long.

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.

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

FOR ANIMAL TREATMENT ONLY

UK authorised veterinary medicinal product.

POM-VPS

To be supplied only on veterinary prescription.

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 GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 52127/5066

17. MANUFACTURER'S BATCH NUMBER

Batch No {number}

18. FURTHER INFORMATION

PREGNANCY AND LACTATION Product may be used at any time during pregnancy.

Can be used in all age groups of sheep and lambs. Can also be used in rams at any time including during the breeding season.

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

BOTTLE (back + front labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukiver 5% w/v Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 50 mg closantel (as closantel sodium)

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

1 Litre
2.5 Litres
5 Litres

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Sheep and lambs
<pictogram of sheep head>

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FLUKE ACTIVITY (*Fasciola hepatica*)

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Gavin Hall
Approved: 12 March 2025