PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON BOX

***Applicable for 2.5, 5 & 10 litre bottles**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacur SC 3%, oral solution
Levamisole hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Levamisole hydrochloride with Selenium and Cobalt

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

2.5 litres, 5 litres, 10 litres

5. TARGET SPECIES

Sheep and Cattle Wormer

6. INDICATION(S)

Oral solution containing 30 mg levamisole hydrochloride per ml with 0.32 mg elemental selenium and 0.72 mg elemental cobalt per ml as nutritional supplements.
For the treatment and control of gastro-intestinal and lungworm infections in sheep and cattle.

For the treatment of sheep and cattle infected with mature and developing immature stages of the following levamisole-susceptible nematode worm species:
Gastrointestinal worms: Trichostrongylus spp., Cooperia spp., Ostertagia spp. (except inhibited Ostertagia larvae in cattle), Haemonchus spp., Nematodirus spp., Bunostomum spp., Oesophagostomum spp., Chabertia spp.
Lungworms: Dictyocaulus spp.
Levacur SC 3% is not effective against Type II Winter scour.
Levacur SC 3% also contains the trace elements selenium and cobalt as an aid in the prevention of selenium and cobalt deficiency.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.
Sheep: 2.5 ml per 10 kg bodyweight (7.5 mg levamisole hydrochloride per kg bodyweight) to be given orally (see table).

		WEIGHT OF SHEEP (Sheep above 60kg should be given a further 1ml for each additional 4kg bodyweight)					
		10kg	20kg	30kg	40kg	50kg	60kg
NUMBER OF SHEEP TO BE TREATED	1	2.5ml	5ml	7.5ml	10ml	12.5ml	15ml
	10	25ml	50ml	75ml	100ml	125ml	150ml
	50	125ml	250ml	375ml	500ml	625ml	750ml
	100	250ml	500ml	750ml	1 litre	1.25 litres	1.5 litres
	500	1.25 litres	2.5 litres	3.75 litres	5 litres	6.25 litres	7.5 litres
	1000	2.5 litres	5 litres	7.5 litres	10 litres	12.5 litres	15 litres
	No. of doses 2.5 litres provides	1000 doses	500 doses	333 doses	250 doses	200 doses	166 doses

Cattle: 2.5 ml per 10 kg bodyweight (7.5 mg levamisole hydrochloride per kg bodyweight) up to a maximum of 75 ml for cattle weighing 300 kg and over.

	WEIGHT OF CATTLE					
	50kg	100kg	150kg	200kg	250kg	300kg & over
DOSE PER ANIMAL	12.5ml	25ml	37.5ml	50ml	62.5ml	75ml max
No. of doses 2.5 litres provides	200 doses	100 doses	66 doses	50 doses	40 doses	33 doses

Treatment should be repeated when reinfestation occurs.
The selenium and cobalt in this product are trace elements of use as nutritional supplements. If a deficiency is suspected consult your veterinary surgeon.

Instructions for use with automatic dosing equipment (e.g. Panacur Drencher):
1. Remove the product container from the carton and shake well.
2. Attach plastic hook through a hole at the base of the bottle and tie strap through diagonally opposite hole at the top, making adjustments as necessary to allow the bottle to hang comfortably on the operator's back.
3. With the product container in the upright position, remove the plain cap and pierce seal with the nozzle cap provided.
4. Screw nozzle cap tightly onto the bottle and firmly attach tube from the automatic dosing equipment to the nozzle.
5. Hang the bottle in the inverted position on the operator's back and carefully prime the gun.

Part used packs may be kept. The nozzle cap should be replaced by the plain cap.

8. WITHDRAWAL PERIOD

Withdrawal period: Animals must not be slaughtered for human consumption during treatment. Sheep and cattle may be slaughtered for human consumption only after 20 days from last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS AND WARNINGS
Levacur SC 3% must not be used in animals producing milk for human consumption. Cattle must not be treated within a period of 14 days before or after treatment with organophosphorus compounds or diethylcarbamazine citrate. The product may be given to young, pregnant and lactating animals, but due regard must always be paid to the animal's physical condition and the presence of inter-current diseases. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. At normal therapeutic dosage side effects are rarely seen. Overdosage may occasionally result in the appearance of cholinergic-type symptoms such as salivation, muscular tremors and head shaking. These effects are more likely to be observed in cattle than in sheep. 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 levamisole has been reported in Teladorsagia, Cooperia and Trichostrongylus species in sheep in a number of countries, including the EU. There are reports of resistance in Haemonchus in sheep outside the EU. Resistance to levamisole has been reported in Teladorsagia species in cattle in developed countries such as New Zealand. 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.
Operator warnings: When using do not eat, drink or smoke. Wash splashes from eyes and skin immediately. Remove any contaminated clothing immediately. Wash hands and exposed skin before meals and after work. Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using this product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately. When a dosing gun is used to administer the product, care should be taken to avoid the occurrence of pharyngitis.
Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. It should also be sought if the product does not achieve the desired clinical effect since other diseases, nutritional disturbances or anthelmintic resistance may be involved. The product should only be used in areas

where deficiencies of selenium and cobalt are likely to occur. In case of doubt, consult your veterinary surgeon.
Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your veterinary surgeon. Not to be diluted. Do not mix with other products.

Class of anthelmintic: 2-LV

10. EXPIRY DATE

EXP: {month/year}
Once opened use within 6 months.
Once opened, use by….

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original container.
Keep the bottle in the outer carton.

12. SPECIFIC 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

[Distribution category]
For animal treatment only. To be supplied only on veterinary prescription.
POM-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Distributed in Northern Ireland by:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4488

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. *FRONT LABEL

***Applicable for 2.5, 5 & 10 litre bottles**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacur SC 3%, oral solution
Levamisole hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Levamisole hydrochloride with Selenium and Cobalt

4. PHARMACEUTICAL FORM

Oral solution

5. PACKAGE SIZE

2.5 litres, 5 litres, 10 litres

6. INDICATION(S)

See back label

7. CONTRAINDICATIONS

See back label

8. ADVERSE REACTIONS

See back label

9. TARGET SPECIES

Sheep and Cattle Wormer

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

See back label

11. ADVICE ON CORRECT ADMINISTRATION

See back label

12. WITHDRAWAL PERIOD

See back label

13. SPECIAL STORAGE PRECAUTIONS

See back label

14. SPECIAL WARNING(S)<User Warnings>

See back label

15. EXPIRY DATE

See back label

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

See back label

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

September 2023

18. See back labelTHE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

See back label

[Distribution category]

See back label

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

See back label

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. *BACK LABEL

***Applicable for 2.5, 5 & 10 litre bottles**

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributed in Northern Ireland by Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacur SC 3%, oral solution
Levamisole hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Levacur SC 3% contains 30 mg levamisole hydrochloride per ml with 0.32 mg elemental selenium and 0.72 mg elemental cobalt per ml as nutritional supplements.

Clear, amber oral solution.

4. PHARMACEUTICAL FORM

See Front Label

5. PACKAGE SIZE

See Front Label

6. INDICATION(S)

Anthelmintic for sheep and cattle.

7. CONTRAINDICATIONS

Levacur SC 3% must not be used in animals producing milk for human consumption. Cattle must not be treated within a period of 14 days before or after treatment with organophosphorus compounds or diethylcarbamazine citrate. The product may be given to young , pregnant and lactating animals, but due regard must always be paid to the animal's physical condition and the presence of inter-current diseases. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. At normal therapeutic dosages side effects are rarely seen. Overdosage may occasionally result in the appearance of cholinergic-type symptoms such as salivation, muscular tremors and head shaking. These effects are more likely to be observed in cattle than in sheep.

8. ADVERSE REACTIONS

Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people.

At normal therapeutic dosages side effects are rarely seen.

9. TARGET SPECIES

See Front Label

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only.
Sheep: 2.5 ml per 10 kg bodyweight (7.5 mg levamisole hydrochloride per kg bodyweight).

	PRACTICAL DOSAGE RECOMMENDATIONS (Sheep above 60kg should be given a further 1ml for each additional 4kg bodyweight)					
WEIGHT OF SHEEP	10kg	20kg	30kg	40kg	50kg	60kg
DOSE	2.5ml	5ml	7.5ml	10ml	12.5ml	15ml

Cattle: 2.5 ml per 10 kg bodyweight (7.5 mg levamisole hydrochloride per kg bodyweight) up to a maximum of 75 ml for cattle weighing 300 kg and over.

	PRACTICAL DOSAGE RECOMMENDATIONS					
WEIGHT OF CATTLE	50kg	100kg	150kg	200kg	250kg	300kg & over
DOSE	12.5ml	25ml	37.5ml	50ml	62.5ml	75ml max.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Sheep and cattle may be slaughtered for human consumption only after 20 days from last treatment.

13. SPECIAL STORAGE PRECAUTIONS

Storage: Do not store above 25ºC. Keep container in outer carton. Store in original container.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

14. SPECIAL WARNING(S)<User Warnings>

Operator warnings: When using do not eat, drink or smoke. Wash splashes from eyes and skin immediately. Remove any contaminated clothing immediately. Wash hands and exposed skin before meals and after work. Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using this product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately. When a dosing gun is used to administer the product, care should be taken to avoid the occurrence of pharyngitis.

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. It should also be sought if the product does not achieve the desired clinical effect since other diseases, nutritional disturbances or anthelmintic resistance may be involved. The product should only be used in areas where deficiencies of selenium and cobalt are likely to occur. In case of doubt, consult your veterinary surgeon.
Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your veterinary surgeon. Not to be diluted. Do not mix with other products.

15. EXPIRY DATE

EXP: {month/year}
Once opened use within 6 months.
Once opened, use by….

16. 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.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

September 2023

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

FOR ANIMAL TREATMENT ONLY

[Distribution category]

POM-VPS

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER

Vm 01708/4488

21. MANUFACTURER'S BATCH NUMBER

BN:

22. OTHER INFORMATION>

Class of anthelmintics 2-LV
Pack sizes: 1, 2.5, 5 or 10 litre multidose containers.
Not all pack sizes may be marketed.

Approved 02 October 2023