MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levamole 75 mg/ml Oral Solution

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

Each ml contains: 75 mg Levamisole HCl, contains Sodium metabisulphite 0.1 % w/v as preservative and Tartrazine (E102) 0.00375 % w/v as colourant.

4. PHARMACEUTICAL FORM

Oral solution

5. PACKAGE SIZE

6. INDICATION(S)

For the treatment and control of roundworms and lungworms (husk) in cattle and sheep.

Levamole 75 mg/ml is a broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep. Levamole 75 mg/ml is effective against mature and developing immature stages of levamisole susceptible major worm species including, Gastro-intestinal worms: *Haemonchus* spp; *Ostertagia* spp (except inhibited *Ostertagia* larvae in cattle); *Nematodirus* spp; *Trichostrongylus* spp; *Cooperia* spp; *Oesophagostomum* spp; *Chabertia* spp; *Bunostomum* spp Lungworms: *Dictyocaulus* spp.

7. CONTRAINDICATIONS

Levamole 75 mg/ml is not effective against type II winter scour.

8. ADVERSE REACTIONS

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. They are more likely to be observed in cattle than in sheep.

9. TARGET SPECIES

Cattle and sheep

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

Levamole 75 mg/ml should be administered as an oral drench. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. Preferably using a gun system, administer a dose at a rate of 7.5 mg Levamisole hydrochloride per kg bodyweight.

DOSAGE GUIDE CATTLE

CATTLE: 1 ML PER 10 KG BODYWEIGHT.

BODYWEIGHT	DOSE
50 kg	5 ml
100 kg	10 ml
150 kg	15 ml
200 kg	20 ml
250 kg	25 ml
300 kg	30 ml

Cattle over 300 kg should be given a further 1 ml for each additional 10 kg bodyweight.

DOSAGE GUIDE SHEEP

SHEEP: 0.5 ML PER 5 KG BODYWEIGHT.

BODYWEIGHT	DOSE
10 kg	1 ml
20 kg	2 ml
30 kg	3 ml
40 kg	4 ml
50 kg	5 ml
60 kg	6 ml

Sheep over 60 kg should be given a further 0.5 ml for each additional 5 kg bodyweight.

11. ADVICE ON CORRECT ADMINISTRATION

Do not mix with other products.

Care should be taken to estimate accurately the bodyweight of animals to be treated before calculating the dosage. 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.

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Cattle and sheep may be slaughtered for human consumption only after 20 days from last treatment. The product must not be used in animals producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Protect from light.

14. SPECIAL WARNING(S)

When using do not eat, drink or smoke. Wash splashes from eyes and skin immediately. If irritation persists consult your doctor. Take off immediately any contaminated clothing. 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.

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:

i) Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.

ii) Underdosing, which may be due to underestimation of bodyweight, 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.

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 and also if the product does not achieve the desired clinical effect, since other diseases, nutritional disturbances or anthelmintic resistance may be involved. When a dosing gun is used to administer the product, care should be taken to avoid occurrences of dosing gun pharyngitis.

15. EXPIRY DATE

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

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

[Distribution category]

POM-VPS

For animal treatment only. 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(S)

Vm 08749/4038

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION

Pack sizes 1 L, 2.5 L and 5 L.

Not all pack sizes may be marketed.

Chemical Group of Anthelmintics: 2-LM

Approved: 05/01/2018