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

Levasure 7.5% w/v Oral Solution

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

Solution containing 7.5% w/v levisamole HCL

4. PHARMACEUTICAL FORM

Oral solution

5. PACKAGE SIZE

6. INDICATION(S)

Levasure 7.5% w/v Oral Solution is a broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep.

Levasure 7.5% w/v Oral Solution is effective against mature and developing immature stages of the following levamisole-susceptible major nematode worm species:-

Gastro-intestinal 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.

7. CONTRAINDICATIONS

Levasure 7.5% w/v Oral Solution is not effective against Type II winter scour.

Cattle should not be treated within a period of 14 days before or after treatment with organophosphorous compounds or diethylcarbamazine citrate.

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.

If the product does not achieve the desired clinical effect, since other diseases, nutritional disturbances or anthelmintic resistance may be involved

9. TARGET SPECIES

Cattle and Sheep

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

Levasure 7.5% should be administered as an oral drench.
Dosing should be carried out accurately, preferably using a gun system, at a rate of 7.5 mg Levamisole HCl per kg bodyweight.

Dosage guide

Cattle : 1 ml per 10 kg bodyweight.
For example : -

Bodyweight	Dose
50 kg (approx. 1 cwt)	5 ml
100 kg (approx. 2 cwt)	10 ml
150 kg (approx. 3 cwt)	15 ml
200 kg (approx. 4 cwt)	20 ml
250 kg (approx. 5 cwt)	25 ml
300 kg (approx. 6 cwt)	30 ml

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

Sheep : 0.5 ml per 5 kg bodyweight.
For example : -

Bodyweight	Dose
10 kg (approx. 22 lbs)	1 ml
20 kg (approx. 44 lbs)	2 ml
30 kg (approx. 66 lbs)	3 ml
40 kg (approx. 88 lbs)	4 ml
50 kg (approx. 110 lbs)	5 ml
60 kg (approx. 132 lbs)	6 ml

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

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked

11. ADVICE ON CORRECT ADMINISTRATION

Not to be diluted. When a dosing gun is used to administer the product, care should be taken to avoid the occurrence of dosing gun pharyngitis.

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Cattle (meat): 20 days
Sheep (meat): 20 days

Not for use in animals producing milk for human consumption

13. SPECIAL STORAGE PRECAUTIONS

Protect from light.

Do not store above 25˚C

14. SPECIAL WARNING(S)

When using, do not eat, drink or smoke. Wash splashes from eyes and skin immediately, if irritation persists. Seek medical advice. 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:

- 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 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. There are reports of resistance in *Haemonchus* in sheep in various parts of the world other than the EU. Resistance to levamisole has been reported in *Teladorsagia* species in cattle in 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.

The product may be given to young, pregnant and lactating animals, but due regard must always be paid to the animals physical condition and the presence of inter-current disease. 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

15. EXPIRY DATE

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in the farm refuse. Used containers should not be recycled.

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 reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4004

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION

Chemical group of anthelmintics 2-LM

Approved: 05/01/2018