

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levamole 75 mg/ml Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Levamisole Hydrochloride 7.5% w/v

Excipient(s):

Sodium Metabisulphite	0.1% w/v
Tartazine (E102)	0.00375% w/v

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
A yellow coloured clear solution.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle and Sheep

4.2. Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep, 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.

Not effective against Type II winter scour.

4.3. Contraindications

Animals should not be treated simultaneously or within 14 days before or after use with Organophosphorous compounds or diethylcarbazine citrate.

4.4. Special warnings for each target species

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. When a dosing gun is used to administer the product, care should be taken to avoid the occurrence of dosing gun pharyngitis.

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 in 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.

4.5. Special precautions for use

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

i. Special precautions for use in animals

For oral use only

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Levamisole can cause idiosyncratic reactions as well as serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea or 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. Wash hands and exposed skin before meals and after work. Remove immediately any contaminated clothing. Wash splashes from eyes and skin immediately. If irritation persists, consult your doctor. When using do not eat, drink or smoke.

4.6. Adverse reactions (frequency and seriousness)

Occasionally at the recommended dose cattle may show signs of lip-licking and slight muscle tremor.

4.7. Use during pregnancy, lactation or lay

Can be safely used during pregnancy and lactation.

4.8. Interaction with other medicinal products and other forms of interaction

Animals should not be treated simultaneously or within 14 days before or after use with Organophosphorous compounds or diethylcarbazine citrate.

4.9. Amounts to be administered and administration route

The product should only be administered as an oral drench.

The 1L, 2.5L and 5L presentations are for use with conventional dosing gun systems.

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

Do not mix with other products.

Dosing should be carried out, at a dose rate of 7.5 mg Levamisole HCl per kg bodyweight.

DOSAGE GUIDE:

Cattle: 1 ml/10 kg bodyweight	
Bodyweight	Dose (ml)
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/5 kg bodyweight	
Bodyweight	Dose (ml)
10 kg (approx. 22 lb)	1 ml
20 kg (approx. 44 lb)	2 ml
30 kg (approx. 66 lb)	3 ml
40 kg (approx. 88 lb)	4 ml
50 kg (approx. 110 lb)	5 ml
60 kg (approx. 132 lb)	6 ml
Sheep over 60 kg should be given a further 0.5 ml for each additional 5 kg bodyweight	

Veterinary advice should be sought:

- a) on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing.
- b) if the product does not achieve the desired clinical effect, since other diseases, nutritional disturbances or anthelmintic resistance may be involved.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

At normal therapeutic dosages side effects are rarely seen. Overdose 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.

4.11. Withdrawal period

Cattle and sheep

Meat and offal: 20 days

Not for use in animals producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic

ATCVet code: QP52AE01

5.1. Pharmacodynamic properties

Levamisole is a ganglion stimulant of the nervous system of nematodes causing neuromuscular paralysis of the parasites. Because it acts on the nervous system it is not ovicidal.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium Metabisulphite

Tartrazine

Disodium Phosphate Dihydrate

Citric Acid Monohydrate

Purified Water

6.2. Incompatibilities

None known.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4. Special precautions for storage

Do not store above 25°C.

Protect from light.

6.5. Nature and composition of immediate packaging

1L, 2.5L and 5L high density polythene containers, with polypropylene closures covered with aluminium foil seals.
Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
Ireland

8. MARKETING AUTHORISATION NUMBER


Vm 08749/4038

9. DATE OF FIRST AUTHORISATION

Date: 12 September 2007

10. DATE OF REVISION OF THE TEXT

Date: April 2014

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