SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levasure 7.5% w/v Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents

Levamisole HCl	7.5% w/v

Excipients

Sodium Metabisulphite	0.1% w/v
Tartrazine 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, Sheep.

4.2 Indications for use, specifying the target species

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.

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

4.3 Contraindications

Animals should not be treated simultaneously or within 14 days before or after the use of Levasure 7.5% w/v Oral Solution with organophosphorous compounds or diethylcarbamazine citrate.

4.4 Special warnings for each target species

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.

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

4.5 Special precautions for use

i. Special precautions for use in animals

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

For oral use only.

ii. Special precautions for the person administering the veterinary medicinal product.

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.

iii. Other precautions

None.

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

Levasure 7.5% w/v Oral solution can be safely used during pregnancy and lactation

4.8 Interaction with other medicinal products and other forms of interaction

See 4.3 above

4.9 Amount(s) to be administered and administration route

The product should only be administered as an oral drench.
Do not mix with other products.
The 1L, 2.5L and 5L presentations are for use with conventional dosing gun systems.

Dosing should be carried out accurately, 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.

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(s)

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

Not for use in animals producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

ATC Vet Code: QP52AE01

5.1 Pharmacodynamic properties

Levasure 7.5% w/v Oral Solution is a drench containing levamisole hydrochloride, an anthelmintic agent. Levamisole hydrochloride is the laevoisomer of tetramisole hydrochloride. It is a broad spectrum anthelmintic with activity against a wide range of gastro-intestinal helminths and lungworms in cattle and sheep. 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 E102
Disodium phosphate dihydrate
Citric acid monohydrate
Water Purified

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

Protect from light.
Do not store above 25˚C

6.5 Nature and composition of immediate packaging

1L, 2.5L and 5L white 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, if appropriate

Any unused veterinary medicinal product or waste materials derived from such 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 08749/4041

9. DATE OF FIRST AUTHORISATION

Date: 13th March 2002

10. DATE OF REVISION OF THE TEXT

Date: July 2013

APPROVED T. NASH **3/07/13**