SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levacur SC 3%, oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Levamisole HCl	3% w/v
Sodium Selenate	0.0766% w/v
(equivalent to Selenium)	0.032% w/v
Cobalt Sulphate Heptahydrate	0.3434% w/v
(equivalent to Cobalt)	0.072% w/v

Excipients:

Sodium Metabisulphite	0.1% w/v
Tartrazine E102	0.0375% w/v

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution
Clear, amber solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep

4.2 Indications for use, specifying the target species

Levacur SC 3% is a broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep.
Levacur SC 3% 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.

Levacur SC 3% is not effective against Type II Winter scour.
The product also contains Selenium and Cobalt as nutritional supplements.

4.3 Contra-indications

Animals should not be treated simultaneously or within 14 days before or after the use of Levacur SC 3% with Organophosphorus compounds or diethylcarbamazine citrate.

4.4 Special warning 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.

- Under dosing, 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.

4.5 Special precautions for use

(i) Special precautions for use in animals

For oral use only

Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your veterinary surgeon. Not to be diluted.

(ii) Special precautions to be taken by the person administering the medicinal product to the 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 any contaminated clothing immediately. Wash splashes from eyes and skin immediately. 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

Levacur SC 3% 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 the use of Levacur SC 3% with Organophosphorus compounds or diethylcarbamazine citrate.

4.9 Amounts to be administered and administration route

The product should only be administered as an oral drench.

Sheep: 2.5 ml per 10 kg (22 lbs) bodyweight
(7.5 mg Levamisole hydrochloride/kg bodyweight).
Practical dosage recommendations:

10 kg	(22 lbs)	2.5 ml	40 kg	(88 lbs)	10.0 ml
20 kg	(44 lbs)	5.0 ml	50 kg	(110 lbs)	12.5 ml
30 kg	(66 lbs)	7.5 ml	60 kg	(132 lbs)	15.0 ml

Sheep over 60 kg should be given a further 1 ml for each additional 4 kg bodyweight.
Cattle: 2.5 ml per 10 kg (22 lbs) bodyweight (7.5 mg Levamisole hydrochloride/kg bodyweight)
Practical dosage recommendations

50 kg	(1 cwt)	12.5 ml	200 kg	(4 cwt)	50.0 ml
100 kg	(2 cwt)	25.0 ml	250 kg	(5 cwt)	62.5 ml
150 kg	(3 cwt)	37.5 ml	300 kg	(6 cwt)	75.0 ml

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

To ensure administration of the 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.

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 periods for the various foodstuffs, including those for which the withdrawal period is zero

Cattle (meat): 20 days
Sheep (meat): 20 days
Not for use in animals producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Levacur SC 3% 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.

The Selenium and Cobalt in this product are trace elements of use as nutritional supplements.

ATC Vet Code: QP 52AE51 – Levamisole combinations

5.2 Pharmacokinetic particulars

Levamisole is a water-soluble compound, which is well absorbed from the oral, subcutaneous, intramuscular and topical routes of administration.
Depending on the route of administration, levamisole is absorbed within 30-60 minutes, reaches a peak plasma level in 1-6 hours and is excreted within 24 hours.

Selenium is absorbed in the duodenum, with virtually no absorption from the abomasum or the rumen. About 40 % of selenium is absorbed by cattle. It is distributed by plasma and is stored in labile forms in all body tissues.

Cobalt is incorporated into Vitamin B_{12} (primarily in the rumen) which is then absorbed, mainly in the lower portion of the small intestine. Only 1 - 3 % of the vitamin produced is absorbed. The absorption of cobalt itself has been estimated at 20 - 95 %.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium hydrogen phosphate dodecahydrate
Citric acid
Sodium Metabisulphite
Tartrazine
Purified water

6.2 Major incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original container

6.5 Nature and composition of immediate packaging

Pack Size:	1L, 2.5L, 5L and 10 Litres
Container:	High density polyethylene bottles
Closure:	High density polyethylene
Cap liner:	Expanded polyethylene
Tamper Evidence:	Closure is tamper-evident for 1L, 2.5L and 5L. Aluminium foil seal for 10L.

Pack size:	1L, 2.5L and 5L Container: High density polyethylene (flexi packs) Closure: Aluminium seal

Not all presentations 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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/5169

9. DATE OF FIRST AUTHORISATION

18 April 2002

10. DATE OF REVISION OF TEXT

November 2025

Gavin Hall
Approved: 06 November 2025