1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanaverm Plus Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Levamisole Hydrochloride 15 mg/ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium Metabisulphite (E223)	0.1% w/v
Tartrazine (E102)	0.00375% w/v
Cobalt sulphate heptahydrate	-
Disodium phosphate dodecahydrate	-
Citric acid monohydrate	-

A bright yellow / orange solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is a broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep. The veterinary medicinal product is effective against mature and developing immature stages of all major stomach and bowel worm species including *Ostertagia* spp., *Nematodirus* spp. and lungworms causing hoose (husk) in cattle and sheep. The veterinary medicinal product contains cobalt as a nutritional supplement.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The veterinary medicinal product is not effective against Type II winter scour.

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.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

The veterinary medicinal product should only be used in areas where deficiencies of cobalt are likely to occur. If in doubt consult your veterinary surgeon.

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. When using do not eat, drink or smoke.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very rare	Lip Licking Muscle Tremor

(<1 animal / 10,000 animals treated, including isolated reports):	

Clinical signs of toxicity may include increased salivation and head tremor in addition to the adverse events specified above.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Animals should not be treated simultaneously with products containing organophosphorus compounds or diethylcarbamazine citrate. Any such treatment should not take place within 14 days before or after the use of this product.

3.9 Administration routes and dosage

For oral use only using suitable dosing equipment.
The dose rate for cattle and sheep is 7.5 mg levamisole hydrochloride per kg bodyweight and 0.4 mg cobalt per kg bodyweight equivalent to 5 ml the veterinary medicinal product per 10 kg bodyweight.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.
The use of suitably calibrated measuring equipment is recommended.

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle and sheep:
Meat and offal: 18 days.

Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AE51

4.2 Pharmacodynamics

The veterinary medicinal product is a drench containing levamisole hydrochloride, a highly effective anthelmintic agent. Levamisole hydrochloride is the laevo-isomer 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.

Cobalt sulphate is included as a trace element to aid in the prevention of cobalt deficiency.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Protect from light.
Do not store above 25°C.

5.4 Nature and composition of immediate packaging

1 litre, 2.5 litre, 5 litre and 10 litre high density polythene containers sealed with polypropylene caps.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10987/008/001

8. DATE OF FIRST AUTHORISATION

01 October 1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27 June 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).