IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10879/006/001**
Case No: 7003839

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Chanelle Animal Health Ltd.

7 Rodney Street, **Liverpool L1 9HZ**, **England**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Chanaverm 7.5% w/v Oral Solution

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **04/09/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanaverm 7.5% w/v Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Levamisole Hydrochloride	7.5	% w/v

Excipients:

Sodium metabisulphite	0.1	% w/v
Tartrazine (E102)	0.00375	% w/v

For a full list of excipients please see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
A clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep

4.2 Indications for use, specifying the target species

Chanaverm 7.5% is a broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep. Chanaverm 7.5% is highly 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.

4.3 Contraindications

None.

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).

4.5 Special precautions for use

Special precaution(s) for use in animals

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the the likelihood of anthelmintic resistance developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved.

Not for use in sheep producing milk for human consumption.

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 .

Chanaverm 7.5% is not effective against Type II winter scours.
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 eye contact occurs, rinse with copious amounts of clean running water. Seek medical advice if irritation persists. Do not eat, drink or smoke when handling or administering the product

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

The product may be safely used in pregnant and lactating animals.

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 Chanaverm 7.5% with organophosphorous compounds or diethylcarbamazine citrate.

4.9 Amounts to be administered and administration route

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

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.

Dosage guide:

Cattle: 1 ml/10 kg bodyweight		**Sheep: 0.5 ml/5 kg bodyweight**	
Bodyweight	**Dose (ml)**	**Bodyweight**	**Dose (ml)**
50 kg (approx. 1 cwt)	5	10 kg (approx. 22 lb)	1
100 kg (approx. 2 cwt)	10	20 kg (approx. 44 lb)	2
150 kg (approx. 3 cwt)	15	30 kg (approx. 66 lb)	3
200 kg (approx. 4 cwt)	20	40 kg (approx. 88 lb)	4
250 kg (approx. 5 cwt)	25	50 kg (approx. 110 lb)	5
300 kg (approx. 6 cwt)	30	60 kg (approx. 132 lb)	6
Cattle over 300 kg should be given a further 1 ml for each additional 10 kg bodyweight		Sheep over 60 kg should be given a further 0.5 ml for each additional 5 kg bodyweight	

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)

Meat and offal : 20 days.

Not for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP52AE01

Pharmacotherapeutic group: Anthelmintics

5.1 Pharmacodynamic properties

Chanaverm 7.5% is a drench containing Levamisole Hydrochloride, a highly effective 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

Disodium hydrogen phosphate dodecahydrate
Citric acid monohydrate
Sodium metabisulphite
Tartrazine (E102)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1, 2.5, 5 and 10 litre high density polyethylene containers, with either polypropylene closures covered with aluminium foil seals or with tamper-evident polypropylene closures.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material will be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.
7 Rodney St.
Liverpool
L1 9HZ
England

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10879/006/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th September 2007

10 DATE OF REVISION OF THE TEXT