Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanaverm Plus Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances		
Levamisole hydrochloride	1.5	% w/v
Excipients		
Sodium metabisulphite (E223)	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 clear yellow/orange solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep.

4.2 Indications for use, specifying the target species

Chanaverm Plus is a broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep. Chanaverm Plus 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. Chanaverm Plus contains cobalt as a nutritional supplement.

4.3 Contraindications

Do not use in animals with known hypersensitivity to levamisole.

4.4 Special warnings for each target species

Chanaverm Plus 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.

4.5 Special precautions for use

Special precautions for use in animals

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

Chanaverm Plus 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.

4.6 Adverse reactions (frequency and seriousness)

Occasionally at the recommended dose cattle may show signs of lip-licking and slight muscle tremors. Clinical signs of toxicity include lip-licking, increased salivation, muscle tremors and head-shaking.

4.7 Use during pregnancy, lactation or lay

Chanaverm Plus may be given to young, pregnant and lactating animals.

4.8 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.

4.9 Amounts to be administered and administration route

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 Chanaverm Plus per 10 kg bodyweight.

To ensure administration of a correct dose, bodyweight 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.
Use properly calibrated dosing equipment.

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

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

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: 18 days.

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, levamisole, combinations
ATCvet code: QP52AE51

5.1 Pharmacodynamic properties

Chanaverm Plus 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cobalt sulphate heptahydrate
Disodium phosphate dodecahydrate
Citric acid monohydrate
Sodium metabisulphite (E223)
Tartrazine (E102)

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

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

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.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/008/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

January 2014