

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Levitape Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substances</u>	<u>% w/v</u>
Levamisole Hydrochloride	3.75
Praziquantel	1.88
<u>Relevant Excipients</u>	
Formaldehyde Solution	0.20
Potassium Sorbate	0.18

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

Levitape is a broad spectrum anthelmintics for use in the treatment and control of nematode and cestode infections. It is effective against mature forms of nematodes, including lungworms, including lungworms and against adult forms of tapeworm in sheep. Levitape should be used in cases of parasitic gastro-enteritis and lungworm disease caused by those organisms sensitive to treatment with praziquantel and / or levamisole hydrochloride.

Stomach and Bowel Worms

Bunostomum sp., *Chabertia* sp., *Cooperia* sp., *Haemonchus* sp., *Nematodirus* sp., *Oesophagostomum* sp., *Ostertagia*, sp., *Trichostrongylus* sp.

Lungworms

Dictyocaulus sp.

Tapeworms

Monezia sp.

4.3 Contraindications

Not for use in sheep producing milk for human consumption.
Not for use in animals that are severely stressed or in ill-health.

4.4 Special warnings for each target species

Due regard must always be given to physical condition, particularly to any animals in advanced pregnancy and/or stress from adverse weather conditions, poor nutrition, penning, handling etc.

4.5 Special precautions for use

Special precautions for use in animals

As with all oral drenches, care must be taken to avoid injury to the throat when using standard drenching equipment. Assess bodyweight as accurately as possible before calculating the dosage. Levitape can be given to debilitated stock (in the absence of inter-current disease). Due regard must always be given to the physical condition of animals undergoing treatment, particularly those in advanced pregnancy and/or under stress from adverse weather conditions, poor nutrition, penning, handling etc.

Veterinary advice should be sought:

- a) on appropriate dosage programmes and stock management to achieve adequate parasite control and to reduce the likelihood of anthelmintics resistance developing;
- b) if the product does not achieve the desired clinical effect, since other diseases, nutritional imbalances or anthelmintics resistance may be involved.

Intensive use or misuse of any anthelmintics can give rise to resistance.

Special Precautions to be taken by the Person Administering the Product to Animals

Any contact with skin or eyes should be washed immediately with water.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

The product is well tolerated at the recommended dosage.

4.7 Use during pregnancy, lactation or lay

Levitape can be given to pregnant and lactating sheep (provided the milk is not to be used for human consumption).

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Sheep: For oral administration at a dose of 1ml per 5 kg bodyweight. This provides a dose of 7.5 mg/kg levamisole hydrochloride and 3.75 mg/kg praziquantel.

Shake well and administer using standard drenching equipment.

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

No clinical signs of toxicity were seen in sheep given 2 times the recommended dosage. At 5 times the recommended dosage, transient and mild excitability was seen in treated sheep.

4.11 Withdrawal Period(s)

Edible tissues: 21 days. Sheep intended for human consumption may be slaughtered after 21 days following treatment.

Not for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Levamisole stimulates both parasympathetic and sympathetic ganglia in parasitic worms, causing a rapid, reversible paralysis which allows them to be expelled from the gut by normal peristaltic action.

Praziquantel causes an almost instantaneous titanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. Praziquantel appears to produce its antiparasitic effects through modulation of the permeability of cell membranes. However, the mechanism of action of praziquantel at a molecular level has not yet been adequately defined. There are also secondary effects including depolarisation of the schistosome tegument, inhibition of glucose uptake, decrease in glycogen content.

5.2 Pharmacokinetic properties

Levamisole is rapidly absorbed from the gastrointestinal tract. In sheep, cattle, pigs and dogs peak levamisole blood levels occur and decrease rapidly.

Residues of the drug are higher and more persistent in liver than in kidney or muscle tissue.

After oral administration praziquantel is quantitatively and rapidly absorbed from the gastrointestinal tract. Only a small portion of unchanged drug reaches the general blood circulation when the drug is administered orally.

Non-metabolised praziquantel shows only very low maximum serum concentrations owing to an intense first pass effect in the liver. Residues tend to be localised in the excretory organs – liver and kidneys. ¹⁴C- praziquantel is hardly taken up at all by the foetus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Anhydrous
Formaldehyde Solution
Polyethylene Glycol 6000
Polyoxyl 40 stearate
Propylene Glycol
Potassium Sorbate
Colloidal Anhydrous Silica
Xanthan Gum
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Two years

6.4 Special precautions for storage

Do not store above 25°C.
Protect from direct sunlight and frost.
Store in original container, tightly closed.
Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

Container: White high density polyethylene pack
Closure: White high density polyethylene screw cap
Pack size: 1 Litre, 2.5 Litre, and 5 Litre.

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

Do not contaminate ponds, waterways or ditches with the product or used containers.
Any unused product or waste materials derived from such products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ancare Ireland Ltd
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10915/10/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th July 2003