Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Arrest Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	
Levamisole Hydrochloride	3.75 % w/v
Fenbendazole	2.50 % w/v
Excipients	
Formaldehyde Solution	0.20 % w/v
Potassium Sorbate	0.18 % w/v

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

For the treatment of roundworm, lungworm and tapeworm infections of sheep caused by:
Gastrointestinal Roundworms: *Bunostomum, Chabertia, Cooperia, Haemonchus, Nematodirus, Oesophagostomum, Ostertagia, Trichostrongylus*
Lungworms: *Dictyocaulus*
Tapeworm: *Moniezia* spp

The product is active against mature and immature parasite stages sensitive to fenbendazole or levamisole.
Fenbendazole is ovicidal and will kill worm eggs.

4.3 Contraindications

Do not use in animals that are severely stressed or in ill-health.

4.4 Special warnings for each target species

Do not administer to sheep under stress or in poor condition.

4.5 Special precautions for use

Assess bodyweight as accurately as possible before calculating dosage recommended.
Do not exceed dose rates. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce the risk, dosing programmes should be discussed with your veterinary surgeon. Care must be taken to avoid injury to the throat when drenching animals.

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

Direct contact with skin should be kept to a minimum.
Wear suitable protective clothing including impermeable rubber gloves.
Wash hands after use.
Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the product, or sore mouth and fever occur shortly afterwards, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not use in sheep producing milk 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

Shake well before use.
Using suitably calibrated drenching equipment, administer orally.

Sheep: 1 ml per 5 kg bodyweight given orally delivers a dose of 7.5 mg/kg levamisole hydrochloride and 5 mg/kg fenbendazole.

For example:

Bodyweight	Dose	
Up to 10 kg	2	ml
10-15 kg	3	ml
16-20 kg	4	ml
21-25 kg	5	ml
26-30 kg	6	ml
Above 30 kg give 1 ml per each 5 kg bodyweight		

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

Symptoms of levamisole overdosing are similar to those of poisoning by organophosphorus compounds: salivation, constriction of the pupils and respiratory distress. Anaphylactic reactions have been reported. Treatment in these cases is with antihistamines. Extremely high dose of fenbendazole (up to 100 x therapeutic dose) would be required to cause any signs of depression and anorexia in sheep.

4.11 Withdrawal Period(s)

Meat and Offal: 21 days
Not permitted for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Fenbendazole – Benzimidazole
Levamisole hydrochloride – Imidazothiazole

ATCvet Code:
QP52A

5.1 Pharmacodynamic properties

The primary mode of action is the prevention of microtubule polymerisation with consequent loss of the parasites' essential enzyme activities. Differential binding affinities between nematode and mammalian tubulin may explain the selective toxicity of Fenbendazole and other Benzimidazoles. 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. High concentrations inhibit the fumerate reductase system, and this effect may contribute to anthelmintic action or be linked to the paralysing effects.

5.2 Pharmacokinetic properties

Fenbendazole is slowly absorbed from the gastrointestinal tract and mostly excreted unchanged in faeces. In sheep, peak Fenbendazole blood levels occur and decrease slowly (tmax ~ 8 to 36 hours); Cmax ~ 53 to 111 micrograms/L; t1/2 ~ 2 to 3 days. The main metabolites in blood plasma are fenbendazole, oxfendazole and fenbendazole sulphone. Target tissue for residues is liver.

Levamisole is rapidly absorbed from the gastrointestinal tract. The percentage of the dose absorbed by the oral route ~ 50%. In sheep, peak levamisole blood levels occur and decrease rapidly (tmax ~ 1 to 2 hours); Cmax ~ 350 to 1000 micrograms/L; t1/2 ~ 3 hours. Residues of the drug are higher and more persistent in liver than in kidney or muscle tissue.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25ºC.
Store in tightly closed original container in upright position.
Protect from light and frost.

6.5 Nature and composition of immediate packaging

White HDPE packs with polypropylene screw caps. Packs contain 1 litre (flat bottom backpack), 2.5 litre (back pack), 5 litre (back pack) and 10 litre (jerrican).

Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

Do not contaminate surface waters or ditches with the product or used containers as this may be dangerous for fish and other aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Ancare Ireland Limited
30 Coolmine Business Park
Clonsilla Road
Dublin 15

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10915/3/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 2001
Date of last renewal: 26th January 2006

10 DATE OF REVISION OF THE TEXT

December 2013