Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Genesis Sheep Drench 0.8 mg/ml abamectin oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Abamectin 0.8 mg/ml

Preservative/Co solvent Benzyl Alcohol 30 mg/mL

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
A clear, pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

For the treatment of gastrointestinal nematodes, lungworms and nasal bots of sheep:

Gastro-intestinal nematodes:
- *Haemonchus contortus* (adult and L_4)
- *Ostertagia circumcincta* (adult, L_4 and inhibited larval stages)
- *Ostertagia trifurcata* (adult)
- *Trichostrongylus axei* (adult)
- *Trichostrongylus vitrinus* (adult and L_4)
- *Trichostrongylus colubriformis* (adult and L_4)
- *Cooperia curticei* (adult and L_4)
- *Nematodirus battus* (adult and L_4)
- *Nematodirus filicollis* (adult)
- *Strongyloides papillosus* (adult)
- *Oesophagostomum venulosum* (adult)
- *Trichuris ovis* (adult)
- *Chabertia ovina* (adult)

Lungworms:
- *Dictyocaulus filaria* (adult and L_4)

Nasal bot
Oestrus ovis (all larval stages)

4.3 Contraindications

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

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.

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.

Resistance to avermectins has been reported in certain nematodes in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals

Intensive use or misuse of anthelmintics may give rise to drug resistance. To reduce this risk, dosing programs should be discussed with your veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- Avoid contact with skin.
- Do not eat, drink or smoke whilst handling the product.
- Operators should wear rubber gloves and boots with a waterproof coat when applying the product
- Protective clothing should be washed after use.
- Wash hands after use.
- Accidental spillage on the skin should be washed off immediately with soap and water.
- If accidental eye exposure occurs, flush the eyes immediately with clean water.
- In case of accidental ingestion, induce vomiting and seek medical care.
- Do not use in other species.

4.6 Adverse reactions (frequency and seriousness)

No adverse effects observed at doses up to four times the recommended treatment dose.

4.7 Use during pregnancy, lactation or lay

The product can be administered during pregnancy in ewes (for information on use in lactating animals, see section 4.11).

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only. The product is ready to use through standard drench guns.
The recommended dose level is 200 µg abamectin per kg bodyweight. One ml of product per 4 kg bodyweight is used.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; 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.

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

Ancare trials showed that a dose of 800 µg/kg caused no adverse reactions with the exception of pupil dilation in treated sheep.

The following signs of toxicity are reported in literature and were associated with excessive over dosing (20 times the recommended therapeutic dose) with Abamectin formulations: drooping of the head and ears, ataxia, goose stepping (forelegs), tail twitching, opisthotonus, lateral recumbency and extensor rigidity.

4.11 Withdrawal Period(s)

Meat and offal: 16 days
Do not use in lactating ewes producing milk for human consumption. Do not use in sheep which are intended to produce milk for human consumption within 60 days of lambing.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides, repellents; Macrocyclic lactones.
ATCvet code: QP54AA02

5.1 Pharmacodynamic properties

Macrocyclic lactones, including Abamectin, have a broad spectrum of activity and are active against mature and immature nematode and arthropod parasites of mammals, fish and other vertebrates. It owes its action to selective and high affinity binding of the molecules to glutamate-gated chloride ion channels that occur in invertebrate nerve and muscle cells. This leads to an increased permeability of the cell membrane to chloride ions with hyperpolarisation of the nerve or muscle cell resulting in paralysis and death of the parasite.

Compounds of this class may also interact with other ligand-gated channels such as those gated by the neurotransmitter - aminobutyric acid (GABA). The margin of the safety for compounds of this class is attributable to the fact that mammals and other vertebrates do not have glutamate-gated chloride ion channels, the avermectin/milbemycin compounds have low affinity for other ligand-gated chloride channels and they do not cross the blood-brain barrier.

Therefore, avermectins kill parasites without adversely affecting their hosts. Reports in the literature describing the effects of avermectins show that concentrations required to affect vertebrates are far in excess of those required to treat relevant parasites.

5.2 Pharmacokinetic properties

The product is formulated in carrier water. Propriety data demonstrated that after oral administrations, radiolabelled abamectin was rapidly absorbed from the gastro-intestinal tract into the systemic circulation following oral administration. There were no apparent differences observed in the plasma kinetics or excretory profile following a single or mixed Abamectin form (i.e. Component B_{1a} alone or mixture of Components B_{1a} and B_{1b}). Greater than 80% of administered radioactivity was eliminated in faeces with elimination in urine being negligible. The half-life of elimination from the plasma was approximately 62 hours. At all time points the highest concentrations of radioactivity were present in liver and fat with much lower concentrations being present in kidney and muscle. By 10 and 14 days the concentrations of radioactivity in many kidney and fat samples were close to or below the limit of detection (approximately 0.003 µg/g). Abamectin B_{1a} was the major component in all tissues with metabolites constituting a significant proportion of the total residue in kidney at early time points and fat at the last time point. At other times in these tissues and at all times in liver and fat, minor metabolites are present which account for a small proportion of the radioactivity.

Concentrations of radioactivity in all tissues were greater than those measured in plasma at the 3 and 7 day time points. These differences were greater for liver (10 fold) than for kidney (3 fold). Concentrations in muscles were only marginally above the levels observed in plasma. It is of interest that the depletion of residues in faeces was correlated to its depletion from tissues and blood. By day 14 post treatments, all levels were below detection limits. The pharmacokinetics profile was:

Parameter:	average
C_{max} (µg equivalents/g):	0.044
T_{max} (h):	24
$T_{½ elim}$ (h):	61.8
Range (h):	12-192
AUC_{O-t} (µg equivalents h/g):	3.755
$AUC_{O-\infty}$ (µg equivalents h/g):	4.611

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Propylene glycol
Glycerol formal
Polysorbate 80
Sodium dihydrogen phosphate
Disodium phosphate dihydrate
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any specific storage precautions.

6.5 Nature and composition of immediate packaging

1.0, 2.5, and 5 L white high density polyethylene backpacks and jerrycans. Not all pack sizes may be marketed.

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

Abamectin is extremely dangerous to fish and other aquatic life. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

The product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Ancare Ireland Ltd.
30 Coolmine Business Park
Clonsilla
Dublin 15

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10915/009/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th December 2009

10 DATE OF REVISION OF THE TEXT

26th October 2010