Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovimec 0.8 mg/ml Oral Solution for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:

Abamectin	0.8	mg
Benzyl alcohol	30.0	mg

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

A broad spectrum endectocide of the avermectin family. For the treatment and control of the following gastro-intestinal nematodes, lungworms and nasal bots roundworms of sheep:

Gastro-intestinal nematodes:

- *Haemonchus contortus* (adult, L_4)
- *Ostertagia circumcincta* (adult, L_4 and inhibited larval stages)
- *Ostertagia trifurcata* (adult)
- *Trichostrongylus axei* (adult)
- *Trichostrongylus vitrinus* (adult and L_4)
- *Trichostronylus colubriformis* (adult and L_4)
- *Cooperia curticei* (adult and L_4)
- *Nematodirus battas* (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 concurrently treat animals with drugs, which can increase GABA activity such as barbital.

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

Dangerous to fish and aquatic life. Do not contaminate surface waters of ditches with the product or used containers.

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 on other species.

4.6 Adverse reactions (frequency and seriousness)

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.

Proprietary data on the product showed no adverse reactions after treatments with up to 4 times the recommended therapeutic dose of the product.

4.7 Use during pregnancy, lactation or lay

Do not use in ewes producing milk for human consumption.

Proprietary data showed that treatment of pregnant ewes over mid to late gestation was safe.

4.8 Interaction with other medicinal products and other forms of interactions

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 micrograms 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. 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

Trials showed that a dose of 800 microgram/kg caused no adverse reactions with the exception of pupil dilation in traded sheep.

4.11 Withdrawal period(s)

Sheep must not be treated within 16 days of slaughter for human consumption.
Do not use in ewes producing milk for human consumption.
Do not use in non-lactating ewes, including pregnant ewes, within 16 days of lambing.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, avermectins
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 ion channels that occur in invertebrate nerve and muscle cells. This leads to an increased permeability of the cell membrane to chloride ions with hyper-polarisation 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 γ-aminobutyric acid (GABA). The margin of the safety for compounds of this class is attributable to the fact the 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, avermectin 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 particulars

The product is formulated in carrier water. Proprietary 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 a 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 microgram/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 it depletion from tissues and blood. By day 14 post treatments, all levels were below detection limits. The pharmacokinetics profile was:

Parameter:	Average:
Cmax (microgram equivalents/g):	0.044
Tmax (h)	24
$T_{½\ elim}$ (h)	61.8
Range (h)	12-192
AUC_{0-t} (microgram equivalent h/g):	3.755
$AUC_{0-\infty}$ (microgram equivalent h/g):	4.611

Environmental properties

Properties which contribute to the environmental safety profile of the avermectins, including abamectin, include the fact that they are hydrophobic, immobile and soil, rapidly photodegraded in water and aerobically degraded in soil to less bioactive compounds; they do not bioaccumulate nor undergo translocation in the environment.

Studies is a variety of terrestrial organisms including bacteria, fungi, higher plants, arthropods, earthworms, birds and mammals have shown that abamectin show little or no toxicity to non-target organisms, other than some coprophagous arthropod larvae. Impact on sensitive, non-target dung arthpod populations is constrained by the typical usage of avermectins.

The proposed use of the product would occur mainly in the summer months when temperatures and sunlight are at their maximum. Therefore the instability of abamectin under these conditions will ensure any residues in the environment are rapidly broken down and will not accumulate.

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 Major 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

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

6.5 Nature and composition of immediate packaging

1 L, 2.5 L and 5 L white 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 derived from the use of such products

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

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

Dispose of waste material by incineration as approved by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Ancare Ireland Ltd.
30 Coolmine Business Park,
Clonsilla Road,
Dublin 15.
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10915/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 June 2005
Dater of last renewal: 02 June 2010

10 DATE OF REVISION OF THE TEXT

January 2020