Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovimectin 10 mg/ml Solution for Injection for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Ivermectin 10 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

For the effective treatment and control of the following species of gastro-intestinal roundworms, lungworms, grubs and lice of sheep:

Gastrointestinal roundworms (adult and L_4):
Teladorsagia (*Ostertagia)circumcincta* including inhibited larvae
O. trifurcata
Haemonchus contortus including inhibited larvae
Trichostrongylus axei (adults)
T. colubriformis and *T. vitrinus* (adults)
Cooperiacurticei
Oesophagostomum columbianum
O. venulosum (adults)
Nematodirus filicollis
Chabertia ovina
Trichuris ovis (adults).

Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagiacircumcincta* are also controlled.

Lungworms:
Dictyocaulus filaria (adult and L_4)
Protostrongylus rufescens (adults)

Nasal Bots (all larval stages)
Oestrus ovis

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use by intramuscular or intravenous administration.
Do not use in non-lactating dairy sheep within 60 days of lambing.

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 results 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 body weight, 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 test(s) 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 ivermectin has been reported in *Teladorsagia circumcincta* in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special Precautions for use in animals

Avermectins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

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

Do not smoke or eat while handling the product.
Wash hands after use.
Direct contact of the product with the skin should be kept to a minimum.
Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.

4.6 Adverse reactions (frequency and seriousness)

Discomfort, sometimes intense but transient, has been observed in some sheep following subcutaneous administration.

4.7 Use during pregnancy, lactation or lay

Pregnancy
The product can be administered during pregnancy in ewes (for information on use in lactating animals, see sections 4.3 and 4.11).

Lactation
Do not use in non-lactating dairy sheep within 60 days of lambing.

Fertility
The fertility of males is not affected by administration of the product.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Ovimectin Injection should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin over the neck in sheep. The injection may be given with any standard automatic or single-dose or hypodermic syringe.

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of sheep. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17 gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals.

Injection of wet or dirty animals is not recommended. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw Ovimectin Injection from the pack.

For young lambs weighing less than 20.0 kg give 0.1 ml per 5 kg. In these lambs, the use of a syringe which can deliver as little as 0.1 ml is recommended.

To ensure administration of a correct dose, body weight 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 over- dosing.

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

Sheep
At dose levels up to 4 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.
In case of overdose, symptomatic treatment should be given. No signs of systemic toxicity were observed in sheep treated with the product at up to 3 times the recommended dose rate

4.11 Withdrawal period(s)

Meat and offal: 42 days
Do not use in lactating sheep producing milk for human consumption. Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QP54AA01Pharmacotherapeutic group: endectocides, avermectins

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization 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 chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic particulars

Maximum plasma concentration

At a dose of 0.3 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.

Excretion: length of time and route
After an injection of 0.3 mg ivermectin per kg, the liver (target tissue) had residues ranging from 160 ppb at 3 days post treatment to 7.2 ppb at 28 days post treatment. The highest residue levels were recovered in fat (from 230 ppb at 3 days post treatment to 13 ppb at 28 days post treatment). Residues in all tissues were below 30 ppb at 28 days post treatment. Radioactive ivermectin was administered to sheep at a dose rate of 0.3 mg per kg. Analyses of the faeces showed that about 99% of the drug and its metabolites are excreted in the faeces, +/- 1% being excreted in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Glycerol Formal

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Multidose high-density polyethylene bottles of 50 ml, 250 ml or 500 ml sealed with bromobutyl seals and plain aluminium overseals containing a clear, colourless sterile solution.
Not all pack sizes may be maketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with national requirements. Do not contaminate lakes or streams as free ivermectin may adversely affect fish and certain water-borne organisms.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/067/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 May 2006
Date of last renewal: 25 May 2011

10 DATE OF REVISION OF THE TEXT

June 2019