1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovimectin 10 mg/ml Solution for Injection for Sheep [IE]
Tizoval 10 mg/ml Solution for Injection for Sheep [ES]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:
Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol
Glycerol formal

A clear, colourless to slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Sheep

3.2 Indications for use for each target species

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

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

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

Lungworms:
Dictyocaulus filaria (adult and fourth-stage larvae)
Protostrongylus rufescens (adult)

Nasal Bots (all larval stages):
Oestrus ovis

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use by intramuscular or intravenous administration.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal or flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each flock should be sought from the responsible veterinarian.

Resistance to ivermectin has been reported in *Teladorsagia circumcincta* in sheep. Therefore, the use of this veterinary medicinal 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.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test (FECRT)).

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authority.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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

Special precautions for the protection of the environment:
See section 5.5.

Other precautions:
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.

3.6 Adverse events

Sheep:

Undetermined frequency (cannot be estimated from the available data):	Discomfort[1]

[1]Sometimes intense but transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The veterinary medicinal product can be used during pregnancy.

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 veterinary medicinal product.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

The veterinary medicinal product should be given only by subcutaneous injection at the recommended dosage level of 200 µg 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 the veterinary medicinal product 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 that can deliver as little as 0.1 ml is recommended.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Accuracy of the dosing device should be thoroughly checked.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 veterinary medicinal product at up to 3 times the recommended dose rate.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 42 days.
Milk: 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

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-gates 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Multiple-dose high-density polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and plain aluminium overseals.

Not all pack sizes may be marketed.

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

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).