1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Turbomec 10 mg/ml Solution for Injection for Cattle and Sheep [IE]
Renomec 10 mg/ml Solution for Injection for Cattle and Sheep [ES]
Cevamec 10 mg/ml Solution for Injection for Cattle and Sheep [FR]
Maximec 10 mg/ml Solution for Injection for Cattle and Sheep [PT]

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, slightly viscous, non-aqueous sterile solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and non-lactating cattle)
Sheep.

3.2 Indications for use for each target species

Cattle:
Treatment of the infections by the following parasites:

Gastrointestinal roundworms (adult and fourth-stage larvae unless otherwise stated):
Ostertagia ostertagi
Ostertagia lyrata
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia oncophora
Cooperia punctata
Cooperia pectinata
Oesophagostomum radiatum
Nematodirus helvetianus (adult only)
Nematodirus spathiger (adult only)

Lungworms:
Dictyocaulus viviparus (adult and fourth-stage larvae)

Warbles (parasitic stages):
Hypoderma bovis, H. lineatum

Mange mites:
Psoroptes ovis (syn. P. communis var. *bovis)*
Sarcoptes scabiei var. *bovis.*

Sucking lice:
Linognathus vituli
Haematopinus eurysternus

Sheep:
Treatment of the infections by the following parasites:

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

Benzimidazole-resistant strains of *Haemonchus contortus* and *Teladorsagia 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.
Do not use in cats and dogs.

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, herd or flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd or flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd or 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 specific herd or flock should be sought from the responsible veterinarian.

Resistance to ivermectin has been reported in *Teladorsagia circumcincta* in sheep, and *Cooperia oncophora* and *Ostertagia ostertagi* in cattle. 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:
Cattle:
To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine it is recommended to administer the veterinary medicinal product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

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, eat or drink while handling the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:
See also 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

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[1] Injection site pain[1]

[1]Transitory discomfort. These reactions have disappeared without treatment within 28 days.

Sheep:

Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[1] Injection site pain[1]

[1]Transitory discomfort. Typically, these reactions disappear without treatment.

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 its local representative 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 administered to beef cows and sheep at any stage of pregnancy.

Fertility:
Fertility 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

A single administration of 0.5 ml per 25 kg bodyweight of cattle or sheep, corresponding to 200 µg ivermectin per kg bodyweight.

For young lambs weighing less than 20 kg, give 0.1 ml per 5 kg. In these lambs, the use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

The administration should be given by subcutaneous injection under the loose skin in front or behind the shoulder in cattle or over the neck in sheep. The volume administered per injection site should not exceed 10 ml.

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.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.

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

Cattle:
Single doses of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

Sheep:
A dose level of 4 mg per kg (20 times the recommended treatment dose) given subcutaneously resulted in ataxia and depression. There is no known antidote. 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.

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

Cattle:
Meat and offal: 49 days.
Milk: Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Sheep:
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 belongs to the avermectin group. 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:
Cattle:
At a dose level of 0.2 mg ivermectin per kg a mean Cmax of 30.43 ng/ml is reached at a mean Tmax of 131 hours. It is also established that ivermectin is distributed mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Sheep:
Following a single administration of the test product at a dose of 0.2 mg ivermectin per kg bodyweight, a mean maximum plasma concentration of 13.0 ng/ml was achieved at approximately four days after treatment.

Excretion: length of time and route
Cattle:
Only about 1-2% is excreted in the urine, the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products. The major metabolite in cattle is 24-hydroxymethyl H2B1a and its fatty acid esters. Almost all of the metabolites of ivermectin are more polar than the parent compound and no single minor metabolite accounts for more than 4% of total metabolites.

Sheep:
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

Multidose 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).