1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovimec 10 mg/ml solution for injection for cattle [IE]
Bovimec B 10 mg/ml solution for injection for cattle [BE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:
Ivermectin 10mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol
Glycerol formal

A clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (Beef and non-lactating cattle)
The veterinary medicinal product can be given to all ages of animals including young calves.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful parasites of cattle:

Gastrointestinal roundworms:
Ostertagia spp. (including inhibited *O. ostertagi*) (adult and fourth-stage larvae)
Haemonchus placei (adult and fourth-stage larvae)
Trichostrongylus spp. (adult and fourth-stage larvae)
Cooperia spp. (adult and fourth-stage larvae)
Nematodirus spp. (adult)

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

Warbles (parasitic stages):
Hypoderma spp.

Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. *bovis.*

Sucking lice:
Linognathus vituli
Haematopinus eurysternus

Persistent activity
Treatment at the recommended dose rate controls re-infection with *Haemonchus placei* and *Cooperia* spp. acquired up to 14 days after treatment, *Ostertagia ostertagi* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of the veterinary medicinal product for grazing animals, it is recommended that calves which are set-stocked in the first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastroenteritis and lungworm disease throughout the grazing season, provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture. Treated animals should always be monitored according to good husbandry practices.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer by the intravenous or intramuscular route.
Do not use in cats and dogs as severe adverse reactions may occur.

3.4 Special warnings

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. It is important that the correct dose is given in order to minimise the risk of resistance. Assess bodyweight as accurately as possible before calculating the dosage.

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 herd.

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

Resistance to ivermectin has been reported in *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:
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.

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

Other precautions:
The veterinary medicinal product has been formulated specifically for use in cattle only. It should not be administered to other species as severe adverse reactions may occur. 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* Injection site pain*

*These reactions have disappeared without treatment within 28 days.

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The veterinary medicinal product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.
Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption. Do not use in pregnant heifers within 60 days prior to calving.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

3.9 Administration routes and dosage

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle. 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. Injection of wet or dirty animals is not recommended. If using a single-dose hypodermic syringe, use a separate sterile needle to withdraw the product from the container.

The veterinary medicinal product should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle. This is equivalent to 1 ml per 50 kg bodyweight. The volume administered per injection site should not exceed 10ml.

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)

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

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: 49 days
Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption.
Do not use in pregnant heifers within 60 days prior to calving.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. 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

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 and the mean half-life in plasma is 142.39 hours.
It is also established that ivermectin is distributed mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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, containing a clear, colourless sterile solution.

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: DD/MM/YYYY

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).