SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus 10/100 mg/ml Solution for Injection for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ivermectin 10mg Clorsulon 100mg

Excipients:

Qualitative composition of excipients and other constituents	
C	Glycerol formal
Propylene glycol	
٨	Monoethanolamine (for pH adjustment)

A clear colourless to pale yellow sterile non-aqueous solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of mixed trematode and nematode or arthropod infestations of the following parasites:

Gastrointestinal roundworms (adult and fourth-stage larvae):

Ostertagia ostertagi (including inhibited larval stages)

Ostertagia lyrata

Haemonchus placei

Trichostrongylus axei

Trichostrongylus colubriformis

Cooperia oncophora

Cooperia punctata

Cooperia pectinata

Bunostomum phlebotomum

Oesophagostamum radiatum

Strongyloides papillosus (adult)

Nematodirus spathiger (adult)

Nematodirus helvetianus (adult)

Lungworms (adult and fourth-stage larvae) *Dictyocaulus viviparou*

Liver fluke (adult):

Fasciola hepatica

Eye worms (adult):

Thelazia spp

Warbles (parasitic stages):

Hypoderma bovis Hypoderma lineatum

Mange mites:

Psoroptes bovis Sarcoptes scabiei var. bovis

Sucking lice:

Linognathus vituli Haematopinus eurysternus Solenopotes capillatus.

The veterinary medicinal product may also be used as an aid in the control of biting lice (*Damalinia bovis*)

and the mange mite Chorioptes bovis, but complete elimination may not occur.

Persistent activity

The veterinary medicinal product given at the recommended dosage of 1ml/50kg bodyweight controls re- infection with *Haemonchus placei*, *Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

3.3 Contraindications

Do not use intramuscularly or intravenously.

This veterinary medicinal product is a low volume product authorised for use in cattle. It must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur, especially Collies, Old English Sheepdogs and related breeds or crosses. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 body weight, misadministration of the product, or lack of calibration of the dosing device (if any). 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 *Ostertagia ostertagi* and *Cooperia* species in cattle within the EU. 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product does not contain any antimicrobial preservative. Swab septum before removing each dose.

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

Do not smoke or eat whilst handling the veterinary medicinal product.

Wash hands after use.

Personal protective equipment consisting of gloves and glasses should be worn when handling the veterinary medicinal product. Direct contact with the skin should be avoided. Take care to avoid self-injection: the product may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

The product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore, repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the	Discomfort ^{1,2}
available data):	Injection site swelling ²

¹Transitory.

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 also the package leaflet for respective contact details.

²Resolves over time without treatment.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used in pregnancy and lactation.

Fertility:

Can be used in breeding animals.

See section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use.

Dosage and duration of treatment

200 µg ivermectin and 2 mg clorsulon per kg bodyweight corresponding to a single dose of 1 ml per 50 kg bodyweight.

Method of administration

The veterinary medicinal product should be administered only by subcutaneous injection under the loose skin in front of or behind the shoulder.

Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications.

A sterile 17 gauge ½ inch (15-20 mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.

When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15°C will greatly increase the ease with which the product can be injected.

When using the 500 ml pack size use only automatic syringe equipment. For the 50 ml pack size, use of a multidose syringe is recommended.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.

To ensure a correct dosage, 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, to avoid under- or over-dosing, they should be grouped according to their bodyweight and dosed accordingly.

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

A dose of 25 ml product per 50 kg bodyweight (25 times the recommended dose level) may result in an injection site lesion, including tissue necrosis, oedema, fibrosis and inflammation. No other drug-related reactions have been observed.

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: 66 days

Milk: Do not use in cattle producing milk for human consumption.

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA51

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides and has a unique mode of action. It has broad and potent antiparasitic activity. It binds 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 hyperpolarisation 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-amino-butyric 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, that the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

Clorsulon is rapidly absorbed in the blood stream. It is bound to the erythrocytes and plasma which are ingested by the fluke. Clorsulon inhibits the glycolytic enzymes in the fluke and deprives it of its main source of metabolic energy.

4.3 Pharmacokinetics

After subcutaneous administration of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight, the plasma profile demonstrated a slow, steady absorption of ivermectin which reached a maximum plasma concentration at a median time of 1.50 days. In

contrast, clorsulon appeared rapidly absorbed with a maximum plasma concentration at a median time of 0.25 days. The terminal half-life for the two active ingredients were determined as follows: Ivermectin approximately 3.79 days and Clorsulon approximately 3.58 days.

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

Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Container material: High density polyethylene

Container closure: Siliconised grey bromobutyl rubber stopper with tamper evident

aluminium overseal.

Container colour: Natural

Container volume: 50ml, 250ml or 500ml

Cardboard box with 1 x 50 ml bottle. Cardboard box with 1 x 250 ml bottle. Cardboard box with 1 x 500 ml bottle.

Not all pack sizes may be marketed.

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

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

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

Do not contaminate surface waters or ditches with the product or used container.

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

Vm 50146/4003

8. DATE OF FIRST AUTHORISATION

19 February 2010

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

April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription. Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved 23 September 2025