SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimamec 5mg/mL Pour-on solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance
Ivermectin 5 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on solution
A clear, blue coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef and non-lactating dairy cattle.

The product at the recommended dosage level of 500 µg ivermectin per kg bodyweight effectively controls the following parasites of cattle:

Gastrointestinal roundworms (adult and fourth stage larvae):
Ostertagia ostertagi
(including inhibited stage)
Haemonchus placei
Trichostrongylus axei T. colubriformis Cooperia spp. *Oesophagostomum radiatum*
Strongyloides papillosus adult
Trichuris spp. adult

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp.

Warbles (parasitic stages):
Hypoderma bovis
H. lineatum

Mites:
Sarcoptes scabiei var. bovis
Chorioptes bovis

Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Damalinia bovis

The product, given at the recommended dosage of 500 micrograms per kg bodyweight, controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment. It also controls horn fly (*Haematobia irritans*) for up to 35 days after treatment.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
The product has been formulated for topical application specifically in cattle.
Do not apply or administer to other species as severe adverse reactions, including fatalities in dogs, may occur.
Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

4.4 Special warnings for each target species

Rainfall before or after treatment will not affect the efficacy of the product.
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 theproduct, 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 macrocyclic lactones (which includes ivermectin) has been reported in *Cooperia* spp. and *Ostertagia ostertagi* in cattle within the EU.

Therefore, the use of this and other similar macrocyclic lactone products should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals
For external use only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.
The product may be irritating to human skin and eyes and the users should be careful not to apply it to themselves or others.
Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use.
Use only in well-ventilated areas or outdoors.
As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water. If irritation persists, seek medical advice and show the package leaflet or label to the physician.
If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Wash hands after use.
Do not smoke, eat or drink while handling the product.

Other precautions
This product is very toxic to aquatic organisms, sediment dwelling organisms, and dung insects. Long-term effects on dung insects caused by continuous or repeated use cannot be excluded.

Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of this product and other products of the same anthelmintic class. Therefore, the repetition of treatment in a pasture during a season should be performed only in the absence of alternative treatment and on veterinary advice.

4.6 Adverse reactions (frequency and seriousness)

Undesirable effects are not expected when the product is used at the recommended dose rate.

4.7 Use during pregnancy, lactation or lay

The product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

4.8 Interaction with other medicinal products and other forms of interaction

Not known.
The product may be used concurrently with foot and mouth disease vaccine or clostridial vaccine.

4.9 Amounts to be administered and administration route

For pour-on use.
Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 micrograms per kg bodyweight).
Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead. The product should be used with appropriate dosing equipment. To ensure administration of correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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

No sign of toxicity appeared up to 5 mg/kg (10 times the recommended dose rate).
No antidote has been identified.

4.11 Withdrawal period(s)

Meat and offal: 15 days.
Do not use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, endectocides, macrocyclic lactones, avermectins; ivermectin
ATC vet code: QP54AA01

5.1 Pharmacodynamic properties

Mechanism of Action

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-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
After topical administration of 0.5 mg ivermectin per kg bodyweight, the plasma samples averaged 1 ng/ml 8 hours post treatment and on days 1 through 7 post dose the average plasma residues were reasonably constant at approximately 3 ng/ml. After day 7 the ivermectin residues gradually decreased to an average of 2 ng/ml at 14 days and 1 ng/ml at 28 days. The concentrations mentioned relate to the main compound of ivermectin, 22,23-dihydroavermectin B1a.
Excretion: length of time and route
After topical administration of 0.5 mg ivermectin per kg bodyweight, liver, the target tissue, generally had the highest residues, averaging 48 ppb at 7 days post dose, 12 ppb at Day 28, and 0 at Day 56. Fat residues averaged 29 ppb at 7 days, 9 ppb at 28 days and 1 ppb on Day 56 after treatment. The dose site residues averaged 13 ppb at Day 7 and dropped to 5 ppb by Day 35. The excretion occurs mainly through faeces and, in a lesser proportion, *via* urine.

5.3 Environmental Properties

Ivermectin is moderately persistent in soil and may accumulate in sediments.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine
Crodamol CAP
Isopropyl Alcohol
Brilliant Blue FCF (E133)
Purified Water

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Flammable - keep away from heat, sparks, open flame or other sources of ignition.
Bottles should remain upright during storage. Cloudiness may result when the product is stored at temperatures below 0°C. Allowing the product to warm at room temperature will restore the normal appearance without affecting efficacy.

6.5 Nature and composition of immediate packaging

High density polyethylene flexipack with a standard polypropylene cap.
Pack sizes: 1 litre, 2.5 litres and 5 litres.
Not all pack sizes may be marketed.

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

EXTREMELY DANGEROUS TO AQUATIC ORGANISMS AND DUNG FAUNA. Do not contaminate surface waters or ditches with product or used container. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4044

9. DATE OF FIRST AUTHORISATION

08 July 2022

10. DATE OF REVISION OF THE TEXT

January 2024

Approved 02 January 2024