1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec 5 mg/ml pour-on solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ivermectin 5 mg

Excipient:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Brillant Blue FCF (E133)	0.00724 mg
Trolamine	
Crodamol CAP	
Isopropyl Alcohol	
Purified Water	

A clear, blue coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and non-lactating dairy cattle).

3.2 Indications for use for each target species

For the treatment of infections with the following species of gastrointestinal roundworms, lungworms, warbles, mites and lice for beef and non-lactating dairy cattle:

Gastrointestinal roundworms (adults and fourth stage larvae):

Ostertagia ostertagi (including inhibited *O. ostertagi*)
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp.
Oesophagostomum radiatum
Strongyloides papillosus (adults only)
Trichuris spp. (adults only)

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms:
Thelazia spp. (adults)

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/kg bodyweight, has persistent activity against *Trichostrongylus axei* and *Cooperia spp* acquired during the 14 days after treatment, only if the whole herd is treated simultaneously. It also has a persistent activity against *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 has a persistent activity on horn flies (*Haematobia irritans*) for 28 days after treatment, partial efficacy may last for up to 35 days post application. Occasionally variable activity may be observed against *Haemonchus placei (L4), Cooperia* spp, *Trichostrongylus axei* and *Trichostrongylus colubriformis*.

3.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
This product is for application to skin surface only, do not give orally or parenterally.

Do not apply or administer to other species as severe adverse reactions, including fatalities in dogs and tortoises/ turtles may occur.

3.4 Special warnings

Cattle should not be treated when hair or hide is wet. Rain falling on cattle in less than two hours after dosing may result in reduced efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment.
Do not apply to areas of skin which may have mange scabs or other lesions or to areas contaminated with mud or manure.
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 ivermectin has been reported in *Cooperia* spp. and *Ostertagia* spp. in cattle within the EU and rise in the frequency of cattle farms with *Haemonchus*-ivermectin resistance has been reported in cattle outside the EU. Therefore, the use of this product 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, including avoidance of interspecies transmission of resistance mutations.

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 product at the end of the period of warble fly activity and before the larvae reach their resting site.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons.
Personal protective equipment consisting of rubber gloves and boots with a waterproof coat should be worn when handling the veterinary medicinal 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 accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Wash hands after use.
HIGHLY FLAMMABLE.
Keep away from heat, spark, open flame or other source of ignition.

Special precautions for the protection of the environment:
Ivermectin is very toxic for aquatic organisms and dung fauna. After treatment, potentially toxic concentrations of ivermectin may be excreted for at least 2 months. Faeces excreted on pasture by treated animals may reduce the abundance of dung fauna which may impact on dung degradation.
In case of repeated treatments with ivermectin (as with products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.
Ivermectin - treated cattle should not have direct access to ponds, streams or ditches for at least two months after treatment.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Application site irritation *

* usually disappear rapidly 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 and Lactation:

The product can be used during pregnancy and lactation. (see section 3.12 for details relating to use in dairy cattle).

Fertility:
The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

3.8 Interaction with other medicinal products and other forms of interaction

None known.
The product may be used concurrently with foot and mouth disease vaccine or clostridial vaccine.

3.9 Administration routes and dosage

For pour-on use.
Dosage: 500 micrograms ivermectin/kg body weight (equivalent to 1 ml of the veterinary medicinal product every 10 kg).
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. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

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

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

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: 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet 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-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.
The exact mechanism of ivermectin resistance has not been elucidated, however, it is thought to involve metabolism by p-glycoproteins and efflux from the cells by ATP-binding cassette (ABC) transporters.
Resistance to ivermectin has been reported in *Cooperia* spp. and *Ostertagia* spp. in cattle within the EU and rise in the frequency of cattle farms with *Haemonchus*-ivermectin resistance has been reported in cattle outside the EU

4.3 Pharmacokinetics

After topical administration of 0.5 mg ivermectin per kg bodyweight to cattle, plasma samples averaged 1 ng/ml 8 hours post treatment and on days 1 through 7 post dose the average plasma concentrations were reasonably constant at approximately 3 ng/ml. After day 7 the ivermectin concentrations were reported to gradually decrease 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.

Liver and fat contain the highest residue levels and muscle the lowest. Ivermectin is mainly excreted in faeces following biliary excretion and, in a lesser proportion, via urine.

Environmental properties:

Ivermectin is very toxic for aquatic organisms and dung fauna. After treatment, potentially toxic concentrations of ivermectin may be excreted for at least 2 months. Faeces excreted on pasture by treated animals may reduce the abundance of dung fauna which may impact on dung degradation.

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: 2 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Store in the original bottle in order to protect from light.
Keep the bottle tightly closed.
Store in a dry place.
HIGHLY FLAMMABLE - keep away from heat, sparks, open flame or other sources of ignition.

Bottles should remain upright during storage.

5.4 Nature and composition of immediate packaging

High density polyethylene bottle sealed with induction seal liners and a tamper evident polypropylene cap.
Pack sizes: 1 L, 2.5 L and 5 L.
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

The veterinary medicinal product should not enter water courses as ivermectin is extremely toxic for aquatic organisms and dung fauna. 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)

VPA22033/077/001

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/12/2021

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

11/04/2024

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).