SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Plus 10 mg/ml + 100 mg/ml Solution for Injection for Cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains
Active substance:

Clorsulon	100 mg
Ivermectin	10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear in colour.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For the treatment of mixed infestations with **adult liver fluke** (*Fasciola hepatica*)
and nematodes or arthropods of the following parasite species and life stages:

Nematodes:
Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia ostertagi (including inhibited larval stages)
O. lyrata
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata
C. pectinata
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
N. spathiger (adult)
Trichuris spp. (adult)

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

Eye worms (adult):
Thelazia spp.

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

Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. *bovis*
Sucking lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

This 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
This product given at the recommended dosage of 0.2 mg per kg 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.

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.

4.3 Contraindications

Do not use intramuscularly or intravenously.
This product is a low volume product authorised for use in cattle.
The product must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur. Some dog breeds (Collies, Old English Sheepdogs and related breeds or crosses) are at particular risk of severe adverse reactions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

For use only in beef cattle and non-lactating dairy cattle

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 bodyweight, 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 macrocyclic lactones (which includes 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.

4.5 Special precautions for use

Special precautions for use in animals

This 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
This product may cause eye and skin irritation.
Avoid contact with skin or eyes.
In case of skin or eye contact, wash exposed area with plenty of clean water. If symptoms persist, seek medical advice.
Do not eat or smoke while handling the product.
Take care to avoid accidental self-injection: the product may cause local irritation and/or pain at the site of injection.
In case of accidental self-injection, seek immediate medical advice and show the information leaflet or the label to the physician.
Wash hands after use.

Other precautions

Ivermectin is highly toxic to aquatic organisms, dung beetles and sediment dwelling insects. Long-term effects on dung insects caused by continuous or repeated use cannot be excluded.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of ivermectin and products of the same anthelmintic class in cattle, sheep and pigs.
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.

Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment.

4.6 Adverse reactions (frequency and seriousness)

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions disappeared without treatment.

4.7 Use during pregnancy, lactation or lay

Can be used in pregnancy and lactation.
Can be used in breeding animals.
See section 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

The recommended dosage is 200 µg ivermectin and 2 mg clorsulon per kg bodyweight corresponding to a single dose of 1 ml per 50 kg bodyweight. Divide doses greater than 10 ml between two injection sites. 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.

Use of 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.

To ensure administration of a correct dose, bodyweight 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.

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 250 ml and 500 ml pack sizes, use only automatic syringe equipment.
For the 50 ml pack sizes, use of a multidose syringe is recommended.

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

A dose of 25ml product per 50kg 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.

4.11 Withdrawal period(s)

Meat and offal: 66 days.
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.

5. PHARMACOLOGICAL PROPERTIES

Endectocides, macrocyclic lactones, avermectins

ATC Vet code: QP54AA51

5.1 Pharmacodynamic properties

Mechanism of Action:

Ivermectin
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.

Clorsulon
Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by *Fasciola spp*. Adult *Fasciola spp.* are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

5.2 Pharmacokinetic particulars

Maximum plasma concentration

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 with mean peak plasma concentrations (C_{max}) of 65.8 ng/ml at a

mean T_{max} of 1.63 days post dose. Average plasma half-life ($t_{½}$) was 4.13 days. In contrast, clorsulon is more rapidly absorbed with mean peak plasma concentrations (C_{max}) of 2.58µg/ml, a mean T_{max} of 0.36 days but shows similar steady elimination to ivermectin with an average plasma half-life of 5.8 days.

5.3 Environmental Properties

Like other macrocyclic lactones, ivermectin has the potential to adversely affect non-target organisms. Faeces containing ivermectin excreted onto pasture by treated animals may reduce the abundance feeding organisms which may impact on the dung degradation.

Ivermectin is very toxic to aquatic organisms and may accumulate in sediments.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal
Monoethanolamine (for pH adjustment)
Propylene glycol

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 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.

6.4 Special precautions for storage

Protect from light.
Keep the container in the outer carton in order to protect from light.
Discard unused material.

6.5 Nature and composition of immediate packaging

Box of 1 bottle of 50ml, 250ml, 500ml or 3 x 500ml natural serum bottles composed of HDPE resin.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local

requirements. EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4038

9. DATE OF FIRST AUTHORISATION

08 May 2019

10. DATE OF REVISION OF THE TEXT

April 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only.
To be supplied only on veterinary prescription.

Approved: 09 May 2024