SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Super Solution for Injection for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:
Ivermectin 10 mg
Clorsulon 100 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
A clean, clear, slightly yellow-coloured liquid

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

The product is indicated for the treatment and control of the following parasites:
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
Liver fluke (adult):
Fasciola hepatica
Eye worms (adult):
Thelazia spp.
Warbles (parasitic stages):
Hypoderma bovis
H. lineatum
Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. *bovis*
Sucking lice:
Linognathus vituli
Haematopinus eurysternus

Solenopotes capillatus

The 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 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 Contra-indications

Do not use intramuscularly or intravenously.
The product is a low-volume product registered for use in cattle. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

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 *Cooperia* spp. in cattle within 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.

4.5 Special precautions for use

(i) Special precautions for use in animals

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

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

Do not smoke, eat or drink while handling the product.
Wash hands after use.
Take care to avoid self injection: the product may cause local irritation and/or pain at the injection site.

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

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.

Please also refer to point 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions have been identified with other products.

4.9 Amounts to be administered and administration route

The product should be administered only by subcutaneous injection at the recommended dosage level of 1 ml/50 kg bodyweight (based on a dosage level of 200 mcg ivermectin plus 2 mg clorsulon per kg bodyweight) under the loose skin in front of, or behind, the shoulder.
Divide doses greater than 10 ml between two injection sites. A sterile 17 gauge 1/2 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.
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. Different injection sites should be used for other parenteral products administered concurrently.
When using the 200 ml, 500 ml and 1000 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

The administration of 25 ml of the product per 50 kg bodyweight (25 x the use level) resulted in an injection site lesion (including tissue necrosis, oedema, fibrosis and inflammation). No other drug-related adverse reactions could be determined.

4.11 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.
Cattle (meat & 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

Pharmacotherapeutic group:

Endectocides, macrocyclic lactones, avermectins

ATCVet 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 the slow, steady absorption of ivermectin with peak plasma levels averaging 23 ng/ml around day 7 post dose. In contrast, clorsulon appeared rapidly absorbed since the first sampling point, 8 hours post dose, had the highest average residues, approximately 2µg/ml.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
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: 5 years.
Shelf-life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Protect from direct sunlight.
Discard unused material.

6.5 Nature and composition of immediate packaging

Multiple-dose rubber-capped polyethylene bottles of 50 ml, 200 ml, 500 ml and 1000 ml. Bottles are stoppered and then either sealed by heat or crimp-sealed with an aluminium cap.

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, if appropriate

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. 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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4253

9. DATE OF FIRST AUTHORISATION

10 January 2013

10. DATE OF REVISION OF THE TEXT

October 2018

Approved 30 October 2018