SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Injection for Cattle and Sheep 10 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ivermectin 10 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A clear, pale, straw-coloured liquid

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Indicated for the effective treatment and control of the following parasites of cattle and sheep:

CATTLE

PARASITE	Adult	L4	Inhibited L4
Gastrointestinal Roundworms			
Ostertagia lyrata	•	•	
Ostertagia ostertagi	•	•	•
Cooperia oncophora	•	•	
Cooperia pectinata	•	•	
Cooperia punctata	•	•	
Haemonchus placei	•	•	
Trichostrongylus axei	•	•	
Trichostrongylus colubriformis	•	•	
Bunostomum phlebotomum	•	•	
Oesophagostomum radiatum	•	•	
Strongyloides papillosus	•		
Nematodirus helvetianus	•		
Nematodirus spathiger	•		
Trichuris spp.	•		

Lungworms		
Dictyocaulus viviparus	•	•
Eye Worms		
Thelazia spp	•	
Warbles		
Hypoderma bovis		
H. lineatum		
Mange Mites		
Psoroptes ovis		
Sarcoptes scabei 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
Given at the recommended dosage of 1ml per 50kg bodyweight, the product controls re-infection with the following nematodes up to the duration shown:

Parasite	**No. of Days After Treatment**
Barbers pole worm - *Haemonchus placei*	14
Small intestinal worm - *Cooperia* spp.	14
Hairworm – *Trichostrongylus axei*	14
Brown stomach worm - *Ostertagia ostertagi*	21
Nodular worm - *Oesophagostomum radiatum*	21
Lungworm – *Dictyocaulus viviparus*	28

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.

SHEEP

PARASITE	**Adult**	**L4**	**Inhibited L4**
Gastrointestinal Roundworms			
Ostertagia circumcincta	•	•	•
O. trifurcata	•	•	
Haemonchus contortus	•	•	•
Trichostrongylus axei	•		
T. colubriformis	•	•	
T. vitrinus	•		
Cooperia curticei	•	•	
Oesophagostomum columbianum	•	•	
O. venulosum	•		
Nematodirus filicollis	•	•	

Chabertia ovina	•	•
Trichuris ovis	•	
Lungworms		
Dictyocaulus filaria	•	•
Protostrongylus rufescens	•	
Nasal Bots		
Oestrus ovis		
Mange Mites		
*Psoroptes ovis**		

Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.

4.3 Contra-indications

Do not inject intravenously or intramuscularly

The product is specifically for use in the target species. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

4.4 Special warnings for each target species

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 *Teladorsagia* spp. in sheep and 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

When treating groups of animals use only an automatic dosing device (with vented draw off apparatus when using the 50ml vial).
Syringes must be filled from the vial through a dry sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 20 times.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. To ensure complete control great care must be taken to avoid re–infestation, as mites may be viable for up to 15 days off the sheep. It is important that all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and untreated flocks must be avoided until at least seven days after treatment.

In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although clinical improvement may be seen, elimination of all mites may not occur.

This product does not contain any antimicrobial preservative.
Swab septum before removing each dose. Use a sterile needle and syringe.

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

Do not smoke, drink or eat 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 site of injection.
In case of accidental self-injection, seek medical advice and show the label or package leaflet to the physician.

4.6 Adverse reactions (frequency and seriousness)

Cattle
Mild and transient discomfort has occasionally been observed in cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed.

Sheep
Discomfort, sometimes intense but usually transient, has been observed in some sheep following subcutaneous administration.

In both species these reactions disappear without treatment.

4.7 Use during pregnancy, lactation or lay

MOLEMEC Injection for Cattle and Sheep can be administered to cows and ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It can be used in breeding ewes, rams, bulls and cows without affecting fertility. MOLEMEC Injection can be given to all ages of animals including young calves and lambs.

4.8 Interaction with other medicinal products and other forms of interaction

MOLEMEC Injection for Cattle and Sheep has been used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.
Adequate vaccination of sheep against clostridial infections is strongly recommended.

4.9 Amounts to be administered and administration route

MOLEMEC Injection for Cattle and Sheep should be given only by subcutaneous injection, using aseptic precautions, at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and in the neck in sheep.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Use this chart as a guide in working out the appropriate dose rate:

CATTLE (1ml/50kg)		**SHEEP** (0.5ml/25kg)	
Bodyweight (kg)	Dose Volume (ml)	Bodyweight (kg)	Dose Volume (ml)
Up to 50	1.0	Up to 5	0.1
51 – 100	2.0	5.1 – 10	0.2
101 – 150	3.0	10.1 – 15	0.3
151 – 200	4.0	15.1 – 25	0.5
201 – 250	5.0	25.1 – 50	1.0
251 – 300	6.0	50.1 – 75	1.5
301 – 350	7.0	75.1 – 100	2.0
351 – 400	8.0		

For cattle weighing over 400kg calculate the dose at the rate of 1ml per 50kg bodyweight

For sheep weighing over 100kg calculate the dose at the rate of 0.5ml per 25kg.

When treating sheep of less than 16kg, seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml. For the treatment of individual sheep, a syringe not exceeding 2.0ml and calibrated in increments of 0.1ml should be used.

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of a sterile 17 gauge x 1/2 inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended.

For the treatment and control of sheep scab, two injections with a seven day interval are required to treat clinical signs of scab and to eliminate mites.

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

Cattle
Single doses of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.
No antidote has been identified, however, symptomatic therapy may be beneficial.

Sheep
Dose levels up to 4 mg ivermectin per kg (20 x the use level), given subcutaneously, resulted in ataxia and depression.

4.11 Withdrawal periods

Cattle (meat & offal): 49 days
Cattle (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.
Sheep (meat & offal): 37 days
Sheep (milk): Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code:

QP54AA01

5.1 Pharmacodynamic properties

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 properties

Maximum plasma concentration

Cattle
At a dose level of 0.2 mg ivermectin per kg a maximum plasma concentration of 35-50 ng/ml is reached in about 2 days and the half-life in plasma is 2.8 days. It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.
Sheep
At a dose level of 0.3 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.

Excretion: length of time and route
Cattle
A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.3 mg ivermectin per kg, the liver (target tissue) had residues ranging from 454 ppb at 2 days post treatment to 11 ppb at 28 days post treatment. All other tissues had lower residues at all time periods: fat > kidney > muscle.

The injection site had residues shortly after treatment, ranging up to 69 ppm at 2 days withdrawal, but by 28 days the average residue was negligible (< 2 ppb). Cattle receiving a single dose of tritium-labelled ivermectin (0.2 - 0.3 mg/kg bodyweight) were slaughtered at 7, 14, 21 and 28 days after dosing.

Composites of faeces collected during the first 7 days after dosing contained almost all the dosed radioactivity. Only about 1-2 % of the dosed radioactivity was excreted in the urine.
Analyses of the faeces showed that about 40-50% of the excreted radioactivity was present as unaltered drug. The remaining 50-60% was present as metabolites or degradation products almost all which were more polar than the ivermectin.

Sheep
A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.3 mg ivermectin per kg, the liver (target tissue) had residues ranging from 160 ppb at 3 days post treatment to 7.2 ppb at 28 days post treatment. The highest residue levels were recovered in fat (from 230 ppb at 3 days post treatment to 13 ppb at 28 days post treatment). Residues in all tissues were below 30 ppb at 28 days post treatment. Radioactive ivermectin was administered to sheep at a dose rate of 0.3 mg per kg. Analyses of the faeces showed that about 99% of the drug and its metabolites are excreted in the faeces, about 1 % being excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
Propylene Glycol

6.2 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.
Following withdrawal of the first dose, use the product within 6 months.
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 closed with grey butyl rubber bungs and then crimp-sealed with an aluminium cap.

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

Container disposal:
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 08327/4251

9. DATE OF FIRST AUTHORISATION

5 August 2011

10. DATE OF REVISION OF THE TEXT

October 2018

ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.

Approved 30 October 2018