SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Injection 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Ivermectin 1.0% w/v (10 mg in 1 ml)

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Beef and non-lactating dairy cattle, sheep and pigs.

4.2 Indications for Use, Specifying the Target Species

Cattle:
For the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and sucking lice in beef cattle and non-lactating dairy cattle.

Gastrointestinal Roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Ostertagia lyrata, Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult)*, Nematodirus spathiger* (adult)*,* and *Trichuris* spp (adults)

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp

Warbles (parasitic stages)**:**
Hypoderma bovis, Hypoderma lineatum

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

Mange Mites:
Psoroptes bovis, Sarcoptes scabiei var *bovis*

The product may also be used as an aid in the control of the biting louse *Damalinia bovis* and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment at the recommended dose rate 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.

Sheep:
For the treatment and control of psoroptic mange (sheep scab), gastrointestinal nematodes, lungworms and nasal bots of sheep.

At the recommended dosage level of 200 mcg ivermectin per kg bodyweight the product effectively controls the following parasites of sheep:

Gastrointestinal Roundworms (adults and fourth stage larvae):
Ostertagia circumcincta, *O. trifurcata, Haemonchus contortus*, *Trichostrongylus axei* (adults), *Trichostrongylus colubriformis*, *Trichostrongylus vitrinus* (adults), *Cooperia curticei, Oesophagostomum venulosum, Oesophagostomum columbianum, Nematodirus filicollis, Chabertia ovina, Trichuris ovis* (adults)

Inhibited larval stages and benzimidazole resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.

Lungworms:
Dictyocaulus filaria (adults and fourth stage larvae)*, Protostrongylus rufescens* (adults).

Mange Mites:
Psoroptes ovis

Nasal Bot:
Oestrus ovis (all larval stages)

Pigs:
For the treatment and control of the harmful species of gastrointestinal roundworms, lungworms, lice and mange mites of pigs. At the recommended dose rate of 300 μg/kg the product provides effective control of the following parasites:

Gastrointestinal Worms:
Ascaris suum (adults and fourth-stage larvae)
Hyostrongylus rubidus (adults and fourth-stage larvae)
Oesophagostomum spp. (adults and fourth-stage larvae)

Strongyloides ransomi (adults and somatic larval stages)

Lungworms:
Metastrongylus spp (adults)

Lice:
Haematopinus suis

Mange Mites:
Sarcoptes scabiei var suis

The product may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

4.3 Contraindications

The product is for administration only by the subcutaneous route and must not be given via other routes. It should not be used in other species than those indicated as severe reactions, including fatalities in dogs, may occur.

4.4 Special Warnings for Each Target Species

Immediately following subcutaneous injection, activity suggesting pain, sometimes intense but usually transient, has been observed in some sheep.

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 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 ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU and it is common in *Haemonchus* in sheep outside the EU. It has been reported in *Cooperia oncophora* in cattle within the EU, in *Teladorsagia* in cattle in developed countries such as New Zealand and *Haemonchus* in cattle outside the EU. Therefore the use of this product should be based on local (regional, farms) 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
In pigs, especially those under 16 kg for which less than a volume of 0.5 ml is indicated, dosing accuracy is important. The use of a suitably calibrated syringe that can accurately deliver 0.1 ml is recommended.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not eat, drink or smoke while handling the product.
Direct contact of the product with the skin should be kept to a minimum. Wash hands after use.

Take care to avoid accidental self-injection: this 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. Tissue swellings at the injection site have been observed. These reactions resolve without treatment.
See also 4.10.

4.7 Use During Pregnancy, Lactation or Lay

The product can be administered to beef cows and ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

The product can be administered to sows at any stage of pregnancy or lactation.

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

4.8 Interaction with Other Medicinal Products and Other Forms of Interaction

None identified.

4.9 Amounts to be Administered and Administration Route

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

Cattle:
Ivermectin should be administered at a dosage rate of 200 μg per kg bodyweight (1 ml to 50 kg bodyweight). It should only be injected subcutaneously in front of or behind the shoulder using aseptic technique. A sterile 17 gauge x ½ inch needle is recommended.

Sheep:
Administer only by subcutaneous injection in the neck at the recommended dosage level of 200 μg ivermectin per kg bodyweight using aseptic technique. Each ml contains 10 mg ivermectin to treat 50 kg of bodyweight. Swab the septum before removing each dose. Use a dry sterile needle and syringe.

Administer subcutaneously only. Inject once under the loose skin in the neck. For the treatment and control of sheep scab (*Psoroptes ovis*) two injections with a seven day interval are required to treat clinical signs of scab and eliminate living mites. Use of a 17 gauge x ½ inch (15-20 mm) needle is suggested. Replace with a fresh sterile needle after every 10-12 animals. Injection of wet or dirty animals is not recommended.

When treating sheep of less than 16 kg seek veterinary advice regarding the use of 1 ml disposable syringes graduated in increments of 0.1 ml.

For the treatment of individual sheep a syringe not exceeding 2.0 ml and calibrated in increments of 0.1 ml should be used.

Pigs:
Administer at a dosage rate of 300 µg per kg bodyweight (1 ml per 33 kg). The product should be injected subcutaneously into the neck using aseptic technique. A sterile 17 gauge x ½ inch needle is recommended.

This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use a dry sterile needle and syringe. For 250 ml, 500 ml and 1 litre pack sizes, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper. Avoid introduction of contamination.

4.10 Overdose (Symptoms, Emergency Procedures, Antidotes), if Necessary

Cattle:
Single doses of 4.0 mg/kg ivermectin (20 times the recommended dosage) administered subcutaneously results in ataxia and depression. No antidote has been identified. Symptomatic treatment may be beneficial.

Sheep:
Dose levels of up to 4 mg/kg given subcutaneously can result in ataxia and depression. Symptomatic treatment may be beneficial.

Pigs:
Ivermectin has a recognised wide safety margin and is known to be safe in all ages of swine. It has no adverse effects on fertility in sows or breeding performance of boars.

Clinical signs of ivermectin toxicity in swine include tremors, bilateral mydriasis and recumbency with some biochemical abnormalities including a transient depression of serum iron. Such changes were only observed when ivermectin was

administered subcutaneously at a dose of 30 mg/kg (100 times the normal therapeutic dose).

4.11 Withdrawal Period

Cattle:
Meat and offal: 49 days.
Do not use in cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

Pigs:
Meat and offal: 28 days.

Sheep:
Meat and offal: 42 days.
Do not use in lactating ewes producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group:	Endectocide
ATC Vet Code:	QP54 AA01

5.1 Pharmacodynamic Properties

Ivermectin is a 22, 23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of 2 homologues: B1a and B1b. It is a parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of this 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 the hyper-polarisation 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 (GABP).

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 lactone 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

Cattle:
At a dose level of 0.2 mg ivermectin per kg, a maximum plasma concentration of 35-50 ng/ml is reached in +/- 2 days and the half-life in plasma is of 2.8 days. It is also established that ivermectin is carried mainly in the plasma (80%). The distribution between plasma and blood cells remains relatively constant.

Sheep:
At a dose level of 0.2 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.

Pigs:
During trials carried out at a dose rate of 0.3 mg/kg ivermectin, a plasma concentration of 10-20 ng/ml was reached in +/- 2 days and the half-life in plasma was 0.5 day.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Glycerol formal
Polyethylene glycol 200

6.2 Incompatibilities

None known.

6.3 Shelf-Life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first broaching the immediate packaging: 28 days

6.4 Special Precautions for Storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose use the product within 28 days. Discard unused material.

6.5 Nature and Composition of Immediate Packaging

50 ml, 100 ml, 250 ml, 500 ml and 1 litre high-density polyethylene vials with bromobutyl bungs and aluminium overseals.
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 product or waste material should be disposed of in accordance with national requirements.
EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with product or used container.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4261

9. DATE OF REVISION OF THE TEXT

May 2026

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Gavin Hall