PARTICULARS TO APPEAR ON THE OUTER PACKAGE (50 ml, 200 ml, 500 ml and 1000 ml Carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Injection for cattle and sheep 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg/ml ivermectin

3. PACKAGE SIZE

50 ml
200 ml
500 ml
1000 ml

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

For the treatment and control of internal and external parasites of cattle and sheep.
For full details see package leaflet.

6. ROUTES OF ADMINISTRATION

CATTLE: The veterinary medicinal product should be given to cattle only by subcutaneous injection in front or behind the shoulder, at the recommended dosage rate of 1 ml per 50 kg bodyweight. A sterile 17-gauge 1/2 inch needle is recommended.

SHEEP: The veterinary medicinal product should be given to sheep only by subcutaneous injection in the neck, at the recommended dosage rate of 0.5 ml per 25 kg bodyweight. A sterile 17-gauge 1/2 inch needle is recommended.

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.

When treating sheep of less than 16 kg, seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml. When treating individual sheep, a syringe, not exceeding 2.0 ml and calibrated in increments of 0.1ml, should be used. When treating groups of animals, use only an automatic dosing device.

7. WITHDRAWAL PERIODS

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

Sheep (meat and offal): 37 days.
Sheep (milk): Do not use in lactating sheep producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.
Protect from direct sunlight.

10. THE WORDS ‘’READ THE PACKAGE LEAFLET BEFORE USE’’

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/5003
Vm 61700/3003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Injection for cattle and sheep 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg/ml ivermectin

3. TARGET SPECIES

Cattle and sheep.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

Sheep (meat and offal): 37 days.
Milk: Do not use in lactating sheep producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.
Protect from direct sunlight.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Molemec Injection for cattle and sheep 10 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance:
10 mg ivermectin.
A clear, pale, straw-coloured liquid.

3. Target species

Cattle and sheep.

4. Indications for use

The veterinary medicinal product is 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 veterinary medicinal 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 in cattle
When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with the veterinary medicinal product at the recommended dose rate of 0.2 mg per kg bodyweight controls re-infection with:

	Prolonged Activity
Dictyocaulus viviparus	up to 28 days
Ostertagia ostertagi	up to 21 days
Oesophagostomum radiatum	up to 21 days
Cooperia spp.	up to 14 days
Trichostrongylus axei	up to 14 days
Haemonchus placei	up to 14 days

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.

5. Contraindications

This veterinary medical product is not for intramuscular or intravenous use.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

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

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.

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.

Special precautions for safe use in the target species:
This veterinary medicinal product has been formulated specifically for use in these target species. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use.
Take care to avoid self-injection as the veterinary medicinal 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.

Pregnancy and lactation:
The veterinary medicinal product to beef cows and ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

The veterinary medicinal product will not affect the fertility of cows, bulls, breeding ewes and rams and can be given to all ages of animals including young calves and lambs.

Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal product 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.

Overdose:
Cattle
Single doses of 4 mg ivermectin per kg (20x the recommended use level) given subcutaneously resulted in ataxia and depression.

Sheep
At dose levels up to 4 mg ivermectin per kg (20x the recommended use level), given subcutaneously, resulted in ataxia and depression.
No antidote has been identified, however, symptomatic therapy may be beneficial.

Major incompatibilities:
None known.

7. Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling (soft tissue) [1]
Very rare(<1 animal / 10,000 animals treated, including isolated reports):	Discomfort[2]

[1] dissappear without treatment

[2] transient after subcutaneous administration

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pain [1]

[1] sometimes intense but usually transient, dissappear without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

The veterinary medicinal product should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg 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.

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 hypodermic syringe.

When using the 500 ml pack size use only automatic syringe equipment.

For example:
Cattle: 1 ml/50 kg bodyweight

Bodyweight (kg)	Dose Volume (ml)
Up to 50	1
51-100	2
101-150	3
151-200	4
201-250	5
251-300	6
301-350	7
351-400	8
401-450	9
451-500	10
501-550	11
551-600	12

Sheep: 0.5 ml per 25 kg bodyweight. For young lambs weighing less than 12 kg give 0.1 ml per 5 kg and the use of a syringe that can deliver as little as 0.1 ml is recommended.

Use the following dosage schedule:

Bodyweight (kg)	Dose Volume (ml)
Up to 25	0.5
26-50	1.0
51-75	1.5
76-100	2.0

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 to eliminate mites.

9. Advice on correct administration

Use of a 17-gauge 1/2 inch needle is suggested. Injection of wet or dirty animals is not recommended. If using a multiple-dose or single-dose hypodermic syringe, use a separate sterile needle to withdraw from the pack.

10. Withdrawal periods

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

Sheep (meat and offal): 37 days.
Milk: Do not use in lactating sheep producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Store below 30 °C.
Protect from direct sunlight.
Following withdrawal of the first dose, use the product within 6 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Do not contaminate surface waters or ditches with product or used container.

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 applicable national collection systems. These measures should help protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 61700/5003
Vm 61700/3003

500 ml. The 500ml pack is soft, collapsible and designed for use with automatic injection equipment. The injection may be given with any standard automatic or single-dose or hypodermic syringe.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
+353 1 291 3985

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du calquet
31000 Toulouse
France

17. Other information

POM-VPS

Gavin Hall
Approved: 01 December 2025