PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

10mg/ml solution for injection (ivermectin).

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle and sheep.

6. INDICATIONS

For full details see package leaflet.

For the treatment and control of internal and external parasites of cattle and sheep.

CATTLE
MOLEMEC Injection for Cattle and Sheep treats and controls gastro-intestinal nematodes, lungworms, warbles, mange mites and sucking lice and aids in the control of biting lice *(Damalinia bovis)* and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

SHEEP
MOLEMEC Injection for Cattle and Sheep treats and controls gastro-intestinal nematodes, lungworms, nasal bots and scab mites (*Psoroptes ovis*).

7. METHOD AND ROUTES OF ADMINISTRATION

DOSAGE AND ADMINISTRATION
This product contains 10 mg/ml of ivermectin.

CATTLE: MOLEMEC Injection for Cattle and Sheep 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: MOLEMEC Injection for Cattle and Sheep 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.

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 400 kg, calculate the dose at the rate of 1 ml per 50 kg bodyweight.

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

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.

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.

8. WITHDRAWAL PERIODS

This product contains 10 mg/ml of ivermectin.

Cattle (meat and offal): 49 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.

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

9. SPECIAL WARNINGS, IF NECESSARY

PRECAUTIONS

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.

User Warnings:
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.

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 for Cattle and Sheep can be given to all ages of animals including young calves and lambs. Ivermectin is a member of the macrocyclic lactone class of endectocides.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Pharmaceutical Precautions:
• This product does not contain any antimicrobial preservative.
• Swab septum before removing each dose.
• Use a dry sterile needle and syringe.
• Protect from direct sunlight and store below 30°C.
• Following withdrawal of the first dose, use the product within six months.
• Discard unused material.
• Use only automatic syringe equipment.

Once opened, used within 6 months.
Once broached, use by:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributed by:

Mole Valley Farmers Ltd.
Station Road, South Molton
North Devon, EX36 3BH

16. MARKETING AUTHORISATION NUMBERS

Vm 08327/4251

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.

To be supplied only on veterinary prescription.

If broken, do not accept.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin 10mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle and sheep.

6. INDICATIONS

For the treatment and control of internal and external parasites of cattle and sheep.

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.

7. METHOD AND ROUTES OF ADMINISTRATION

TREATMENT: This product contains 10 mg/ml of ivermectin.
Inject subcutaneously at the rate of:
Cattle: 1 ml per 50 kg - **Sheep:** 0.5 ml per 25 kg

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE.

8. WITHDRAWAL PERIODS

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

9. SPECIAL WARNINGS, IF NECESSARY

PRECAUTIONS
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.

Vial stoppers must not be broached more than 20 times. See package leaflet for details of appropriate syringes for use with MOLEMEC Injection for Cattle and Sheep.

MOLEMEC Injection for Cattle and Sheep belongs to the macrocyclic lactone class of endectocides.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Pharmaceutical Precautions:
• This product does not contain any antimicrobial preservative.
• Swab septum before removing each dose.
• Use a dry sterile needle and syringe.
• Protect from direct sunlight and store below 30°C.
• Following withdrawal of the first dose, use the product within six months.
• Discard unused material.
• Use only automatic syringe equipment.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributed by:

Mole Valley Farmers Ltd.
Station Road, South Molton
North Devon, EX36 3BH

16. MARKETING AUTHORISATION NUMBERS

Vm 08327/4251

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR: Molemec Injection for cattle and sheep 10mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

DISTRIBUTED BY:
Mole Valley Farmers Ltd.
Station Road, South Molton
North Devon, EX36 3BH

BATCH RELEASE SITE
Boehringer Ingelheim Animal Health France SCS
4 Chemin du calquet
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

10 mg/ml ivermectin.

4. INDICATIONS

For the treatment and control of internal and external parasites of cattle and sheep.

MOLEMEC Injection for Cattle and Sheep 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		

MOLEMEC Injection for Cattle and Sheep 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 MOLEMEC Injection for Cattle and Sheep 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

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.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cattle and sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

MOLEMEC Injection for Cattle and Sheep 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. Do not inject intravenously or intramuscularly.

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, multiple-dose or single-dose hypodermic syringe.

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

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, two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate all living mites.

9. ADVICE ON CORRECT ADMINISTRATION

TREATMENT PROGRAMMES
Seek advice of your veterinary surgeon.

10. WITHDRAWAL PERIODS

Cattle (meat and offal): 49 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.

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

11. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL PRECAUTIONS

• This product does not contain any antimicrobial preservative.

• Swab septum before removing each dose.

• Use a dry, sterile needle and syringe.

• Protect from direct sunlight and store below 30°C.

• Following withdrawal of the first dose, use the product within 6 months.

• When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

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

• Discard unused material.

• 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.

• Keep out of reach of children.

12. SPECIAL WARNINGS

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

Injection of wet or dirty animals is not recommended.

If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw from the pack.

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.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. Following treatment of infected sheep, 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 to ensure all sheep which have been in contact with infected sheep are treated. Contact between treated infected and non-treated, non-infected flocks must be avoided until at least 7 days after the last treatment.

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.

USER WARNINGS
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.

FURTHER INFORMATION
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.

Immediately following subcutaneous injection, activity suggesting pain, sometimes intense but usually transient, has been observed in some sheep. These reactions disappeared without treatment.

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.

Further information is available on request.

Ivermectin is a member of the macrocyclic lactone class of endectocides.

For Animal Treatment Only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM-VPS

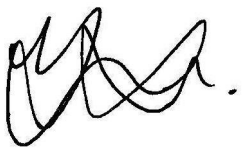
Vm 08327/4251

To be supplied only on veterinary prescription.

INTRODUCTION
MOLEMEC Injection for Cattle and Sheep is an injectable parasiticide.
One dose effectively controls internal and external parasites that impair livestock health and productivity.

PRODUCT DESCRIPTION
MOLEMEC Injection for Cattle and Sheep is a ready-to-use, sterile, non-aqueous 10mg/ml solution of ivermectin.
Ivermectin is a derivative from the avermectin family of highly active, broad-spectrum antiparasitic agents which are isolated from fermentation of *Streptomyces avermitilis*.

PACKAGE INFORMATION
MOLEMEC Injection for Cattle and Sheep is available in one ready-to-use size: 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.
Full list of pack sizes: 50ml, 200ml, 500ml, 1L.
Not all pack sizes may be marketed.



Approved: 28 May 2020