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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOLEMEC super solution for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sterile solution for injection containing 10 mg/ml ivermectin and 100 mg/ml clorsulon

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1000 ml
500 ml
200 ml
50 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and control* of gastro-intestinal roundworms, lungworms, adult liver fluke, eyeworms, warbles, mites* and lice* of beef and non-lactating dairy cattle.
*For details see package leaflet.

- MOLEMEC Super kills adult and immature gastro-intestinal roundworms, including inhibited *Ostertagia ostertagi*.
- MOLEMEC Super kills adult and immature lungworms (*Dictyocaulus viviparus*).
- MOLEMEC Super controls re-infection with *Haemonchus placei* and *Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.
- MOLEMEC Super kills adult liver fluke (*Fasciola hepatica*).
- MOLEMEC Super kills adult eyeworms (*Thelazia spp.*).
- MOLEMEC Super kills warble larvae (*Hypoderma bovis* and *H. lineatum*).
- MOLEMEC Super kills mange mites (*Sarcoptes scabiei* var. *bovis*, *Psoroptes bovis*).
- MOLEMEC Super kills sucking lice (*Linognathus vituli, Haematopinus eurysternus* and *Solenopotes capillatus*).
- MOLEMEC Super 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.

MOLEMEC Super contains ivermectin and clorsulon. 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IMPORTANT: READ PACKAGE LEAFLET
BEFORE USE.

DOSAGE AND ADMINISTRATION

Administration:
Inject SUBCUTANEOUSLY ONLY behind the shoulder. Divide doses greater than 10 ml between two injection sites. A sterile 17 gauge 1/2-inch needle is recommended. 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 (injectable) products.

Dosage:
1 ml per 50 kg bodyweight (based on a recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kg bodyweight). For example:

Bodyweight (kg)	Dose Volume (ml)	Doses per Pack			
		1000 ml	500 ml	200 ml	50 ml
Up to 50	1	1000	500	200	50
51-100	2	500	250	100	25
101-150	3	332	166	66	16
151-200	4	250	125	50	12
201-250	5	200	100	40	10
251-300	6	166	83	33	8

Over 300 kg bodyweight, give 1 ml per 50 kg bodyweight.

8. WITHDRAWAL PERIODS

- Cattle (meat) - 66 days.
- Do not use in cattle producing milk for human consumption, or in non-lactating dairy cows including pregnant heifers within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications
- Do not use this product intramuscularly or intravenously**.**
- Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

Precautions

- Different injection sites should be used for other parenteral products.
- 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.
- 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 have disappeared without treatment. Divide doses greater than 10 ml between two injection sites to reduce occasional discomfort or site reaction.

This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe. When using the 200 ml, 500 ml and 1000 ml pack sizes, use only automatic syringe equipment.

10. EXPIRY DATE

Expiry date:
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Following withdrawal of the first dose, use the product within 6 months. Discard unused material.

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 containers. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

POM-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4253

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

MOLEMEC Super is a low-volume product registered for use in cattle.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (1000 ml, 500 ml, 200 ml and 50 ml labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOLEMEC super solution for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin 10 mg/ml and Clorsulon 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1000 ml
500 ml
200 ml
50 ml

5. TARGET SPECIES

Cattle

6. INDICATIONS

For the treatment and control* of gastro-intestinal roundworms, lungworms, adult liver fluke, eyeworms, warbles, mites* and lice* of beef and non-lactating dairy cattle.
*IMPORTANT: READ PACKAGE LEAFLET BEFORE USE

7. METHOD AND ROUTE OF ADMINISTRATION

USE DOSAGE AND ADMINISTRATION
Dosage:
1 ml per 50 kg bodyweight (based on a recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kg bodyweight).

Administration:
Inject SUBCUTANEOUSLY ONLY behind the shoulder. Divide doses greater than 10 ml between two injection sites. Different injection sites should be used for other parenteral products.

8. WITHDRAWAL PERIODS

Cattle (meat) - 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.

9. SPECIAL WARNINGS, IF NECESSARY

Read package leaflet before use.

PRECAUTIONS
Do not use this product intramuscularly or intravenously. 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.
MOLEMEC Super 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.
This product does not contain an antimicrobial preservative.
Swab the septum before removing each dose. Use a dry, sterile needle and syringe.
When using the 200 ml, 500 ml and 1000 ml pack sizes, use only automatic syringe equipment.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Following withdrawal of the first dose, use the product within 6 months. Discard unused material.

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 containers.
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

For animal treatment only.
To be supplied only on veterinary prescription.

POM-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4253

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR: MOLEMEC super solution for injection for cattle

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Distributed by:
Mole Valley Farmer 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 super solution for injection for cattle

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

Sterile solution for injection containing 10 mg/ml ivermectin and 100 mg/ml clorsulon

A clean, clear, slightly yellow-coloured liquid

4. INDICATION(S)

For the treatment and control* of gastro-intestinal roundworms, lungworms, adult liver fluke, eyeworms, warbles, mites** and lice** of beef and non-lactating dairy cattle.

*MOLEMEC Super is indicated for the effective treatment and control of the following harmful species of gastro-intestinal roundworms, lungworms, liver fluke, eyeworms, warbles, mites and lice.

Gastro-intestinal roundworms (Adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited larval stages), *O. lyrata, Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus (*adult), *N. spathiger* (adult), and *Trichuris spp.* (adult).

Lungworms (Adult and fourth-stage larvae)
Dictyocaulus viviparus
Liver fluke (Adult)

Fasciola hepatica

Eyeworms (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

MOLEMEC Super 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.

MOLEMEC Super contains ivermectin and clorsulon. 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

Prolonged activity
MOLEMEC Super remains highly effective against newly ingested larvae of important parasites grazed from the pasture for an extended period after treatment. Treatment with MOLEMEC Super at the recommended dose rate controls re-infection with *Haemonchus placei, Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment; *Ostertagia* spp. and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

5. CONTRAINDICATIONS

Do not use this product intramuscularly or intravenously.
Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

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.

Studies have demonstrated a wide safety margin and the recommended use level had no adverse effect on breeding performance.

7. TARGET SPECIES

Cattle.

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

Administration:
MOLEMEC Super is to be given SUBCUTANEOUSLY ONLY.
Inject under the loose skin behind the shoulder (see illustration). Use of a 17 gauge, 1/2 inch (15-20 mm) needle is suggested. Injection of animals with wet or dirty hides is not recommended.

If using a hypodermic syringe, use a separate sterile needle to withdraw MOLEMEC Super from the pack. 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.

Dosage:
MOLEMEC Super should only be given by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kg of bodyweight. Each ml contains 10 mg of ivermectin and 100 mg of clorsulon, sufficient to treat 50 kg of bodyweight. Use the following dosage schedule:

Body Weight kg	**Dose volume ml**	**Bodyweight kg**	**Dose volume ml**
Up to 50	1.0	301-350	7.0
51-100	2.0	351-400	8.0
101-150	3.0	401-450	9.0
151-200	4.0	451-500	10.0
201-250	5.0	501-550	11.0
251-300	6.0	551-600	12.0

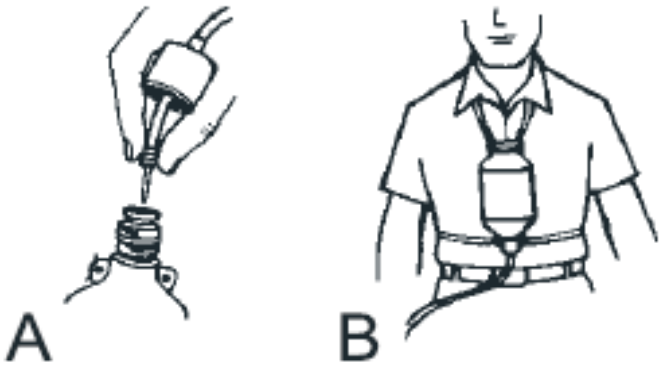
Divide doses greater than 10 ml between two injection sites. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

9. ADVICE ON CORRECT ADMINISTRATION

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

When using the 200 ml, 500 ml and 1000 ml pack sizes, use only automatic syringe equipment.
Instructions for use with automatic injection equipment:

- Disinfect all needles and syringes before using by boiling in clean water for 15-20 minutes.
- Boiled needles should be stored in an antiseptic solution before use and changed frequently when injecting cattle.
- The use of a sterile draw-off assembly is recommended with this product. Handle carefully to avoid contamination.
- Connect the plastic tube firmly to the dosing syringe. Use a stepped adaptor if needed.
- Remove cap from bottle and disinfect rubber stopper with alcohol or other suitable chemical disinfectant. Hold bottle upright and fully insert draw-off needle into centre of rubber stopper (see illustration A).
- Secure firmly with screw-on cap attached to tube.
- Hang bottle comfortably in inverted position from neck (see illustration B), shoulder or belt.
- Gently prime injector. Equipment is now ready for use.
- After use, remove draw-off assembly and flush out entire apparatus with clean water before storing.
- Store partly-used bottle in carton to protect from light. Do not re-use empty bottles.
- If the connecting tube is used a second time, it should also be boiled for 15-20 minutes before use along with the injecting syringe and needles.



10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Protect from light. Following withdrawal of the first dose, use product within 6 months. Discard unused material.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

i) Special Precautions for use in animals

For use only in beef cattle and non-lactating dairy cattle.

Divide doses greater than 10 ml between two injection sites to reduce occasional discomfort or site reaction.

Molemec Super 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.
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 were determined.

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.

ii) Special precautions for the person administering the veterinary medicinal product to 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.

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

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 containers. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Introduction:
MOLEMEC Super Injection for Cattle is an injectable parasiticide. One low-volume dose effectively kills internal and external parasites that impair the health and productivity of cattle. The product contains ivermectin and the flukicide, clorsulon. Its convenience, broad-spectrum efficacy, and wide safety margin make it an ideal product for parasite control of cattle.

Product description:
MOLEMEC Super is a sterile, non-aqueous solution containing 10 mg/ml ivermectin and 100 mg/ml clorsulon for parenteral administration. At the rate of 1 ml per 50 kg bodyweight by subcutaneous injection, this formulation delivers the recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kg bodyweight.

Mode of action:
Ivermectin paralyses and ultimately kills parasitic nematodes, arachnids and insects, including warbles, by its effect on the nervous systems of these parasites. At therapeutic doses, ivermectin has no adverse effect on cattle since it does not readily penetrate their central nervous systems. Ivermectin belongs to the avermectin class of anthelmintic endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents. Clorsulon works by interrupting the metabolic activity of liver fluke and inhibiting enzymes that are essential for their energy production.

For animal treatment only.
Keep out of the sight and reach of children.

MOLEMEC Super is a low-volume product registered for use in cattle.

Presentations: 50 ml, 200 ml, 500 ml, 1000 ml

Not all pack sizes may be marketed.

Further information available upon request

Vm 08327/4253

POM-VPS

To be supplied only on veterinary prescription.

Approved 06 October 2020