

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Pour-On for Cattle 5 mg/ml Pour-On Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Ivermectin 5 mg

Excipients

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef and non-lactating dairy cattle.

The product at the recommended dosage level of 500 µg ivermectin per kg bodyweight effectively controls the following parasites of cattle:

Gastrointestinal roundworms (adult and fourth stage larvae):

Ostertagia ostertagi (including inhibited stage)

Haemonchus placei

Trichostrongylus axei

T. colubriformis

Cooperia spp.

Oesophagostomum radiatum

Strongyloides papillosus (adult)

Trichuris spp. (adult)

Lungworms (adult and fourth stage larvae):

Dictyocaulus viviparus

Eyeworms (adult):

Thelazia spp

Warbles (parasitic stages):

Hypoderma bovis
H. lineatum

Mange mites:

Sarcoptes scabiei var. *bovis*
Chorioptes bovis

Lice:

Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Damalinia bovis

The product given at the recommended dosage of 500 µg/kg bodyweight, controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment, and *Dictyocaulus viviparus* (lungworm) acquired up to 28 days after treatment.

It also controls horn fly (*Haematobia irritans*) for up to 35 days after treatment.

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.

4.3 Contra-indications

Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

The product has been formulated for topical application specifically in cattle. Do not apply or administer to other species as severe adverse reactions, including fatalities in dogs, may occur.

Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

4.4 Special warnings for each target species

Rainfall before or after treatment will not affect the efficacy of the product. Do not apply to areas of skin which may have mange, scabs or other lesions or to areas contaminated with mud or manure.

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 macrocyclic lactones (which includes ivermectin) has been reported in *Cooperia* spp. and *Ostertagia ostertagi* in cattle within the EU. Therefore, the use of this and other similar macrocyclic lactone products 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

For external use only.

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

HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

May be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons.

Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product.

Wash all protective clothing after use.

If accidental skin contact occurs, wash the affected area immediately with soap and water. If irritation persists, seek medical advice and show the package leaflet or label to the doctor.

If accidental eye exposure occurs, flush the eyes immediately with plenty of water and get medical attention.

Do not smoke or eat while handling the product.

Wash hands after use.

Use only in well-ventilated areas or outdoors.

4.6 Adverse reactions (frequency and seriousness)

Undesirable effects are not expected when the product is used at the recommended dose rate.

4.7 Use during pregnancy, lactation or lay

The product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

Please also refer to point 4.4.

4.8 Interaction with other medicinal products and other forms of interaction

Not known.

May be used concurrently with foot and mouth disease vaccine or clostridial vaccine.

4.9 Amounts to be administered and administration route

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 µg/kg bodyweight).

Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

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

Dosing cup with Measure-Squeeze-Pour System (250 ml bottle and 1 litre pack)

The 250 ml pack contains one 25 ml dosing cup and one dip tube.

The 1 litre pack contains one 60 ml dosing cup and one dip tube.

Insert the dip tube into base of the dosing cup. Leave the “slotted end” of the dip tube exposed in the bottom of the bottle.

Unscrew bottle cap from the top of the bottle. Screw the dosing cup onto the top of the bottle.

Measure: To select the correct dose rate, rotate the adjuster cap at the top of the cup in either direction to position the dose indicator to the weight of the animal you want to treat. When body weight is between markings, use the higher setting.

Squeeze the bottle gently to fill the dosing cup to the required dose. Release your grip and any excess will return to the bottle.

Pour: Apply the full dose by tipping and pouring along the back line of the animal until the dosing cup is empty.

The dosing cup should not remain attached to the bottle when not in use. Detach the dosing cup after each use and replace the bottle cap.

Collapsible Pack (2.5 litre pack x2 in a carton)

If the carton is opened for purpose of sale in single 2.5 L units, a package insert must be provided with each transaction.

Connect the pour-on applicator to the collapsible pack as follows:

- Attach the open end of the draw-off tubing to the pour-on applicator.**
- Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap that has the draw-off tubing. Tighten this draw-off cap.

- Gently prime the pour-on applicator, checking for leaks.
- Follow manufacturer's directions for correct use and care of the equipment.

** An applicator compatible with the formulation is available for use with the 2.5 litre pack of Molemec Pour-On. Other applicators may be incompatible with the formulation, resulting in locking, incorrect dosage and leakage.

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

No sign of toxicity appeared in trials up to 5 mg/kg (10 times the recommended dose rate). No antidote has been identified.

4.11 Withdrawal periods

Meat and offal: 15 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.

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

After topical administration of 0.5 mg ivermectin per kg bodyweight, the plasma samples averaged 1 ng/ml 8 hours post treatment and on days 1 through 7 post dose the average plasma residues were reasonably constant at approximately 3 ng/ml. After day 7 the ivermectin residues gradually decreased to an average of 2 ng/ml at 14 days and 1 ng/ml at 28 days. The concentrations mentioned relate to the main compound of ivermectin, 22,23-dihydroivermectin B_{1a}.

Excretion: length of time and route

Cattle

After topical administration of 0.5 mg ivermectin per kg bodyweight, liver, the target tissue, generally had the highest residues, averaging 48 ppb at 7 days post dose, 12 ppb at Day 28, and 0 at Day 56. Fat residues averaged 29 ppb at 7 days, 9 ppb at 28 days and 1 ppb on Day 56 after treatment. The dose site residues averaged 13 ppb at Day 7 and dropped to 5 ppb by Day 35. The excretion occurs mainly through faeces and, in a lesser proportion, via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triethanolamine
Isopropyl alcohol
Crodamol Cap

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Avoid extremes of temperature.
Protect from light.
Store in tightly closed original container.
Store upright.
The dosing cup should not be stored attached to the bottle when not in use.
Remove the cup after each use and replace with the bottle cap.
If stored at temperatures below 0°C, Molemec Pour-On may appear cloudy.
Allowing the product to warm at room temperature will restore the normal appearance without affecting efficacy.

6.5 Nature and composition of immediate packaging

Measure-squeeze-pour high density polyethylene bottles of 250 ml and 1 litre, and high density polyethylene collapsible packs of 2.5 litres, containing a clear, slightly yellow-coloured solution.
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, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4247

9. DATE OF FIRST AUTHORISATION

24 May 2011

10. DATE OF REVISION OF THE TEXT

October 2018

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved 30 October 2018