BOVIMEC
5 MG/ML CATTLE POUR-ON SOLUTION
Ivermectin 5mg/ml

DATA SHEET

INDICATIONS FOR USE

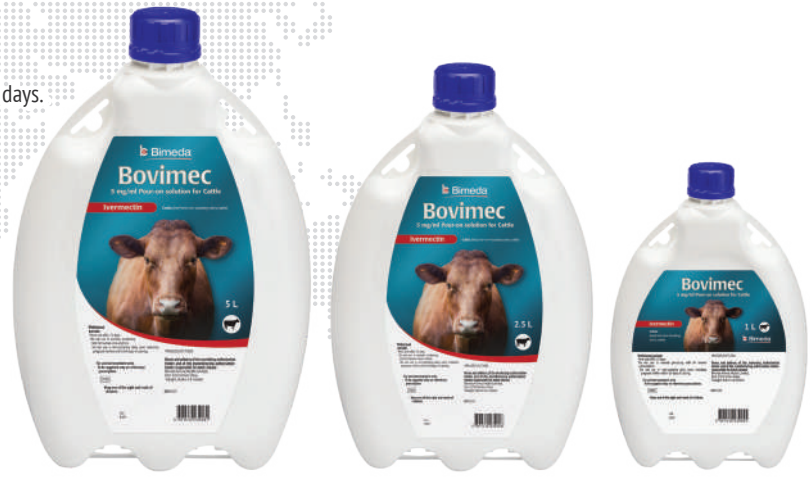
For the treatment of infections with the following species of gastrointestinal roundworms, lungworms, warbles, mites and lice for beef and non-lactating dairy cattle:

Gastrointestinal roundworms (adults and fourth stage larvae)
Lungworms (adult and fourth stage larvae)
Eyeworms
Warbles (parasitic stages)
Mites
Lice

Persistent Activity:
- *Trichostrongylus axei & Cooperia* spp
- *Ostertagia ostertagi* & *Oesophagostomum radiatum*: 21 days
- Lungworm (*Dictyocaulus viviparus*) : 28 days
- Horn Flies (*Haematobia irritans*): 28 days with partial efficacy up to 35 days.

BENEFITS

- **Delivers effective control against a wide range of external and internal parasites**
- **Easy to apply**
- **Persistent activity against several parasites**



LIST No	UNIT PACKAGE
1BIM338	1 L
1BIM337	2.5 L
1BIM336	5 L

See reverse for Administration & Dosage

Bovimec

5 mg/ml Pour-on solution for Cattle

Ivermectin 5mg/ml

ACTIVE SUBSTANCE
Ivermectin 5 mg/ml. Pour-on solution.

TARGET SPECIES
Cattle. (*beef and non-lactating dairy cattle)*

INDICATIONS FOR USE, SPECIFYING THE TARGET SPECIES
For the treatment of infections with the following species of gastrointestinal roundworms, lungworms, warbles, mites and lice for beef and non-lactating dairy cattle:
Gastrointestinal roundworms (adults and fourth stage larvae): *Ostertagia ostertagi* (including inhibited *O. ostertagi*),*Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia* spp., *Oesophagostomum radiatum, Strongyloides papillosus* (adults only), *Trichuris* spp. (adults only).
Lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus.*
Eyeworms: *Thelazia* spp. (adults).
Warbles (parasitic stages): *Hypoderma bovis, H. lineatum.*
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 micrograms/kg bodyweight, has persistent activity against *Trichostrongylus axei* and *Cooperia* spp acquired during the 14 days after treatment, only if the whole herd is treated simultaneously. It also has a persistent activity against *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment. It also has a persistent activity on horn flies (*Haematobia irritans*) for 28 days after treatment, partial efficacy may last for up to 35 days post application. Occasionally variable activity may be observed against *Haemonchus placei* (L4), *Cooperia* spp, *Trichostrongylus axei* and *Trichostrongylus colubriformis.*

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE
For pour-on use.

DOSAGE
500 micrograms ivermectin/kg body weight (equivalent to 1 ml of the veterinary medicinal product for every 10kg bodyweight.

ADMINISTRATION
The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead. The product should be used with appropriate dosing equipment. To ensure administration of correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

WITHDRAWAL PERIOD(S)
Meat and offal: 15 days.
Do not use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

CONTRAINDICATIONS
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
This product is for application to skin surface only, do not give orally or parenterally.
Do not apply or administer to other species as severe adverse reactions, including fatalities in dogs and tortoises/ turtles may occur.

SPECIAL WARNINGS
Cattle should not be treated when hair or hide is wet. Rain falling on cattle in less than two hours after dosing may result in reduced efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment.
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 appropriatetests (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 has been reported in *Cooperia* spp. and *Ostertagia* spp. in cattle within the EU and rise in the frequency of cattle farms with *Haemonchus*-ivermectin resistance has been reported in cattle outside 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, including avoidance of interspecies transmission of resistance mutations.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS
To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of the period of warble fly activity and before the larvae reach their resting site.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS
The product 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 rubber gloves and boots with a waterproof coat when applying the product.
Protective clothing should be washed after use.
Use only in well-ventilated areas or outdoors.
As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Wash hands after use.
HIGHLY FLAMMABLE.
Keep away from heat, spark, open flame or other source of ignition.

OTHER PRECAUTIONS:
Ivermectin is very toxic for aquatic organisms and dung fauna. After treatment, potentially toxic concentrations of ivermectin may be excreted for at least 2 months. Faeces excreted on pasture by treated animals may reduce the abundance of dung fauna which may impact on dung degradation.
In case of repeated treatments with ivermectin (as with products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.
Ivermectin - treated cattle should not have direct access to ponds, streams or ditches for at least two months after treatment.

ADVERSE REACTIONS
Occasionally slight irritation at the application site may occur. However, usually these irritations rapidly disappear without treatment.

USE DURING PREGNANCY OR LACTATION
The product can be used during pregnancy and lactation.
The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS
None known.
The product may be used concurrently with foot and mouth disease vaccine or clostridial vaccine.

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

PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Antiparasitic products, Endectocides, macrocyclic lactones, avermectins; ATC vet code: QP54AA01

PHARMACODYNAMIC PROPERTIES
Ivermectin is a member of the macrocyclic lactone class of endectocides. 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.
The exact mechanism of ivermectin resistance has not been elucidated, however, it is thought to involve metabolism by p-glycoproteins and efflux from the cells by ATP-binding cassette (ABC) transporters.
Resistance to ivermectin has been reported in *Cooperia* spp. and *Ostertagia* spp. in cattle within the EU and rise in the frequency of cattle farms with *Haemonchus*-ivermectin resistance has been reported in cattle outside the EU.

PHARMACOKINETIC PARTICULARS
After topical administration of 0.5 mg ivermectin per kg bodyweight to cattle, plasma samples averaged 1 ng/ml 8 hours post treatment and on days 1 through 7 post dose the average plasma concentrations were reasonably constant at approximately 3 ng/ml. After day 7 the ivermectin concentrations were reported to gradually decrease 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-dihydroavermectin B1a.
Liver and fat contain the highest residue levels and muscle the lowest. Ivermectin is mainly excreted in faeces following biliary excretion and, in a lesser proportion, via urine.

ENVIRONMENTAL PROPERTIES:
Ivermectin is very toxic for aquatic organisms and dung fauna. After treatment, potentially toxic concentrations of ivermectin may be excreted for at least 2 months. Faeces excreted on pasture by treated animals may reduce the abundance of dung fauna which may impact on dung degradation.

LIST OF EXCIPIENTS
Trolamine, Crodamol CAP, Isopropyl Alcohol, Brillant Blue FCF, (E133) Purified Water

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

SHELF-LIFE
Shelf-life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 6 months.

SPECIAL PRECAUTIONS FOR STORAGE
Store in the original container in order to protect from light. Keep the container tightly closed.
Store in a dry place.
HIGHLY FLAMMABLE - keep away from heat, sparks, open flame or other sources of ignition. Bottles should remain upright during storage.

NATURE AND COMPOSITION OF IMMEDIATE PACKAGING
High density polyethylene container sealed with induction seal liners and a tamper evident polypropylene cap.
Pack sizes: 1 L, 2.5 L and 5 L.
Not all pack sizes may be marketed.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS
EXTREMELY DANGEROUS TO AQUATIC ORGANISMS AND DUNG FAUNA. Do not contaminate surface waters or ditches with product or used container. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION HOLDER
Bimeda Animal Health
Limited, Unit 2/3/4 Airton
Close, Tallaght, Dublin 24,
Ireland

MARKETING AUTHORISATION NUMBER(S)
VPA22033/077/001

LEGAL CATEGORY
POM

TAKE TIME  OBSERVE LABEL DIRECTIONS

www.bimeda.ie

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