# BIMECTIN

## 1% W/V SOLUTION FOR INJECTION

**Ivermectin 1% w/v**

# DATA SHEET

## INDICATIONS

For the effective treatment and control of the following harmful parasites of cattle, sheep and pigs:

**Cattle**

Gastrointestinal roundworms (adult and fourth-stage larvae): *Ostertagia* spp. (including inhibited *O. ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult), *N. spathiger* (adult), *Trichuris* spp (adult).
Lungworms (adult and fourth-stage larvae): *Dictyocaulus viviparus*
Eye worms (adult): *Thelazia* spp.
Warbles: *Hypoderma bovis*, *H. lineatum*
Mange mites: *Psoroptes bovis*, *Sarcoptes scabiei var. bovis*
Sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*
May also be used as an aid in the control of the mange mite *Chorioptes bovis* and biting lice *Damalinia bovis*, but complete elimination may not occur.
Persistent Activity: Treatment at the recommended dose rate can control re-infection with *Haemonchus placei* 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* up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of the product for grazing animals, it is recommended that calves which are set-stocked in the first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastroenteritis and lungworm disease throughout the grazing season, provided they are set-stocked, all the calves included in the programme and that no untreated cattle are added to the pasture. Treated animals should always be monitored according to good husbandry practices.

**Sheep**

Gastrointestinal roundworms (adult and fourth-stage larvae): *Ostertagia circumcincta* including inhibited larvae, *O. trifurcate*, *Haemonchus contortus* including inhibited larvae, *Trichostrongylus axei* (adults), *T. colubriformis* and *T. vitrinus* (adults), *Cooperia curticei*, *Oesophagostomum columbianum*, *O. venulosum* (adults), *Nematodirus filicollis*, *Chabertia ovina*, *Trichuris ovis* (adults).
Lungworms: *Dictyocaulus filaria* (adult and fourth-stage larvae), *Protostrongylus rufescens* (adults)
Nasal Bots (all larval stages): *Oestrus ovis*

**Pigs**

Gastrointestinal roundworms (adult and fourth-stage larvae): *Ascaris suum*, *Hyostrongylus rubidus*, *Oesophagostomum* spp., *Strongyloides ransomi* (adult and somatic larval stages)
Lungworms: *Metastrongylus* spp. (adults)
Lice: *Haematopinus suis*
Mange mites: *Sarcoptes scabiei var. suis*

## BENEFITS

- For use in cattle, sheep and pigs
- Contains ivermectin for the effective treatment and control of a range of endo and ectoparasites
- 50ml, 250ml and 500 ml pack sizes

| LIST No | UNIT PACKAGE | CASE SIZE |
|---|---|---|
| 1BIM068 | 50 ml | 12 |
| 1BIM069 | 250 ml | 6 |
| 1BIM070 | 500 ml | 6 |


**See reverse for Administration & Dosage**

# Bimectin Injection

## 1% w/v Solution for Injection

### ACTIVE SUBSTANCES
Ivermectin 1.0 % w/v. Solution for injection.
A clear, colourless, slightly viscous, non-aqueous sterile solution.

### TARGET SPECIES
Cattle, sheep and pigs.

### INDICATIONS FOR USE
For the effective treatment and control of the following harmful parasites of cattle, sheep and pigs:

**Cattle**
Gastrointestinal roundworms (adult and fourth-stage larvae): *Ostertagia* spp. (including inhibited *O. ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult), *N. spathiger* (adult), *Trichuris* spp (adult).
Lungworms (adult and fourth-stage larvae): *Dictyocaulus viviparus*
Eye worms (adult): *Thelazia* spp.
Warbles: *Hypoderma bovis*, *H. lineatum*
Mange mites: *Psoroptes bovis*, *Sarcoptes scabiei var. bovis*
Sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*
May also be used as an aid in the control of the mange mite *Chorioptes bovis* and biting lice *Damalinia bovis*, but complete elimination may not occur.
Persistent Activity: Treatment at the recommended dose rate can control re-infection with *Haemonchus placei* 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* up to 28 days after treatment.
To obtain optimal benefit from the persistent activity of the product for grazing animals, it is recommended that calves which are set-stocked in the first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastroenteritis and lungworm disease throughout the grazing season, provided they are set-stocked, all the calves included in the programme and that no untreated cattle are added to the pasture. Treated animals should always be monitored according to good husbandry practices.

**Sheep**
Gastrointestinal roundworms (adult and fourth-stage larvae): *Ostertagia circumcincta* including inhibited larvae, *O. trifurcate*, *Haemonchus contortus* including inhibited larvae, *Trichostrongylus axei* (adults), *T. colubriformis* and *T. vitrinus* (adults), *Cooperia curticei*, *Oesophagostomum columbianum*, *O. venulosum* (adults), *Nematodirus filicollis*, *Chabertia ovina*, *Trichuris ovis* (adults).
Lungworms: *Dictyocaulus filaria* (adult and fourth-stage larvae), *Protostrongylus rufescens* (adults)
Nasal Bots (all larval stages): *Oestrus ovis*

**Pigs**
Gastrointestinal roundworms (adult and fourth-stage larvae): *Ascaris suum*, *Hyostrongylus rubidus*, *Oesophagostomum* spp., *Strongyloides ransomi* (adult and somatic larval stages)
Lungworms: *Metastrongylus* spp. (adults)
Lice: *Haematopinus suis*
Mange mites: *Sarcoptes scabiei var. suis*

### AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE
The product should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and over the neck in sheep.
At the recommended dosage level of 300 mcg ivermectin per kg of bodyweight, the product should be given only subcutaneously in the neck of pigs.
Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep and 33 kg of bodyweight of pigs.
The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17-gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals.
Injection of wet or dirty animals is not recommended. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw the product from the container. Massage the injection site after administration of the product.
In young pigs, especially those below 16 kg for which less than 0.5 ml of the product is indicated, dosing accuracy is important.
The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.
In young lambs weighing less than 20.0 kg give 0.1 ml per 5 kg. In these lambs the use of a syringe with can deliver as little as 0.1 ml is recommended.
To ensure administration of a 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 over- dosing.

### WITHDRAWAL PERIOD
**Cattle**
Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.
**Sheep**
Meat and offal: 42 days.
Do not use in lactating sheep producing milk for human consumption. Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.
**Pigs**
Meat and offal: 28 days.

### CONTRAINDICATIONS
Do not use in animals with known hypersensitivity to the active ingredient. Do not use by intramuscular or intravenous administration.

### SPECIAL WARNINGS FOR EACH TARGET SPECIES
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.
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 ivermectin has been reported in *Teladorsagia circumcincta* in sheep and *Ostertagia ostertagi* in cattle. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

### SPECIAL PRECAUTIONS FOR USE IN ANIMALS
The product has been formulated specifically for use in cattle, sheep and pigs. 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 PRODUCT TO ANIMALS
Take care to avoid self-administration: the product may cause local irritation and/or pain at the site of injection. Direct contact of the product with the skin should be kept to a minimum. Do not smoke or eat while handling the product. Wash hands after use.
When using the 250 ml and 500 ml pack sizes, use only automatic syringe equipment. For the 50 ml pack size, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw off needle is recommended to avoid excessive broaching of the stopper.

### ADVERSE REACTIONS
**Cattle** - Transient discomfort has occasionally been observed in cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed.
**Sheep** - Discomfort, sometimes intense but usually transient, has been observed in some sheep immediately following subcutaneous administration.
**Pigs** - Mild and transient discomfort has occasionally been observed in pigs following subcutaneous injection.
All these reactions disappeared without treatment.

### USE DURING PREGNANCY AND LACTATION
Pregnancy - The product can be administered to beef cows, sheep and pigs at any stage of pregnancy.
Lactation - Do not use in dairy cows or sheep producing milk for human consumption. Do not use in non-lactating dairy cows or sheep within 60 days of calving/lambing. The product can be used in sows during lactation.
Fertility - Fertility is not affected by administration of the product.

### INTERACTION WITH OTHER MEDICINAL PRODUCTS
The product can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

### OVERDOSE
Cattle - Single doses of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.
Sheep - At dose levels up to 4 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression. No signs of systemic toxicity were observed in sheep treated with the product at up to 3 times the recommended dose rate, soft tissue swellings at the injection site were observed.
Pigs - A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.
In the case of overdosage, symptomatic treatment should be given.

### PHARMACODYNAMIC PROPERTIES
Therapeutic group: Endectocide
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.

### PHARMACOKINETIC PARTICULARS
Maximum plasma concentration:
Cattle: At a dose level of 0.2 mg ivermectin per kg a maximum plasma concentration of 35-50 ng/ml is reached in ± 2 days and the half-life in plasma is 2.8 days. It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.
Sheep: At a dose of 0.3 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.
Pigs: During trials carried out at a dose rate of 0.3 mg ivermectin per kg bodyweight, peak plasma concentrations were reached in 3 (±0.5) days and the drug persisted in plasma for up to 28 days.
Excretion: length of time and route:
Cattle: Only about 1-2% is excreted in the urine the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products.
Sheep: Radioactive ivermectin was administered to sheep at a dose rate of 0.3 mg per kg. Analyses of the faeces showed that about 99% of the drug and its metabolites are excreted in the faeces, +/- 1% being excreted in the urine.
Pigs: Biliary excretion is also the major route of ivermectin excretion in pigs.

### 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: 28 days.

### SPECIAL PRECAUTIONS FOR STORAGE
This veterinary medicinal product does not require any special storage conditions.

### SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. The product should not enter water courses as this may be dangerous to fish and other aquatic organisms.

### MARKETING AUTHORISATION HOLDER
Bimeda Animal Health Limited,
2, 3 & 4 Airton Close,
Airton Road,
Tallaght,
Dublin 24,
Ireland
Call Lo Call 1850 51 52 53

### MARKETING AUTHORISATION NUMBER
**VPA22033/056/001**

### LEGALLY CATEGORY
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**Use Medicines Responsibly.**
**A full product SPC is available on request from Bimeda or alternatively can be found on the HPRA website**

TAKE TIME  OBSERVE LABEL DIRECTIONS

**www.bimeda.ie**

*Bimeda data sheet created: April 2021*