

BIMECTIN PLUS

Solution For Injection

Ivermectin 10mg/ml and Clorsulon 100mg/ml

DATA SHEET



INDICATIONS

For the treatment and control of the following parasites:

Gastrointestinal Roundworms (adult and fourth-stage larvae):

- *Ostertagia* spp. (including inhibited *O. ostertagi*)
- *Haemonchus placei*
- *Trichostrongylus axei*
- *Trichostrongylus colubriformis*
- *Cooperia* spp.
- *Bunostomum phlebotomum*
- *Oesophagostomum radiatum*
- *Strongyloides papillosus* (adult only)
- *Nematodirus helvetianus* (adult only)
- *Nematodirus spathiger* (adult only)
- *Toxocara vitulorum*
- *Trichuris* spp. (adult only)

Lungworm (adult and fourth-stage larvae):

- *Dictyocaulus viviparus*

Liver Fluke (adult):

- *Fasciola hepatica*

Eye Worms (adult):

- *Thelazia* spp.

Warbles (parasitic stages):

- *Hypoderma bovis*
- *H. lineatum*

Mange mites:

- *Psoroptes bovis*
- *Sarcoptes scabiei* var. *bovis*

Sucking Lice:

- *Linognathus vituli*
- *Haematopinus eurstermus*
- *Solenopotes capillatus*

The veterinary medicinal product may also be used as an aid in the control of biting lice (*Damalinea bovis*) and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

BENEFITS

- Broad spectrum treatment and control of internal and external parasites in cattle
- 3-in-1 solution for adult liver fluke, worms and ectoparasites in 1 injection

LIST No	UNIT PACKAGE	CASE SIZE
1BIM156	50 ml	12
1BIM157	250 ml	6
1BIM182	300 ml	8
1BIM158	500 ml	6
1BIM240	1250 ml Promo pack	1



See reverse for Administration & Dosage

Bimectin Plus

Solution for Injection - Ivermectin 10mg/ml and Clorsulon 100mg/ml



PRESENTATION

A clear colourless to pale yellow sterile non-aqueous solution containing Ivermectin (10mg/ml) and Clorsulon (100mg/ml)

TARGET SPECIES

Cattle.

INDICATIONS FOR USE

Cattle

For the treatment and control of the following parasites:

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

Strongylodes papillosus (adult)

N. spathiger (adult)

N. helvetianus (adult)

Trichuris spp (adult)

Toxocara vitulorum

Lungworm (adult and fourth-stage larvae)

Dictyocaulus viviparus

Liver fluke (adult):

Fasciola hepatica

Eye worms (adult):

Thelazia spp.

Warbles (parasitic stages):

Hypoderma bovis

H. lineatum

Mange mites:

Pсорoptes bovis

Sarcoptes scabiei var. *bovis*

Sucking ilce:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus.

The veterinary medicinal product may also be used as an aid in the control of biting lice (*Damalinea bovis*) and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Persistent activity

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with the product 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* acquired up to 28 days after treatment.

WITHDRAWAL PERIOD(S)

Cattle Meat and Offal: 66 days Milk: Do not use in cattle producing milk for human consumption, including pregnant animals, intended to produce milk for human consumption.

CONTRA-INDICATIONS

- This product is not to be used intramuscularly or intravenously.
- Bimectin Plus Injection is a low volume product authorised for use in cattle. It must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
- Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS FOR 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 (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.

SPECIAL PRECAUTIONS FOR USE

i) Special precautions for use in animals

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance

developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved.

Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications.

Swab septum before removing each dose. Avoid the introduction of contamination during use.

When using the 250 ml and 500 ml pack sizes, use only automatic syringe equipment. For the 50 ml pack size, the use of a multidose syringe is recommended.

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

Do not eat, drink or smoke while handling the product.

Wash hands after use.

Take care to avoid self-administration; the product may cause local irritation and/or pain at the site of injection.

In the event of accidental skin contact, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)

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.

USE DURING PREGNANCY AND LACTATION OR LAY

The product is safe for use at any stage of pregnancy or lactation. However, the product is not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk 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.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

None known

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. The 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.

The product should be given only by subcutaneous injection at the recommended dosage level of 1 ml/50 kg bodyweight (based on a dosage level of 200 mcg ivermectin plus 2 mg clorsulon per kg bodyweight) under the loose skin in front of, or behind, the shoulder.

Divide doses greater than 10 ml between two injection sites. A sterile 17 gauge ½-inch (15-20 mm) 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 products.

PHARMACODYNAMIC PROPERTIES

Ivermectin

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.

CLORSULON

Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by *Fasciola* spp. Adult *Fasciola* spp. are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

PHARMACOKINETIC PARTICULARS

Maximum plasma concentration

After subcutaneous administration of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight, maximum plasma concentrations of ivermectin (C_{max}: 65.80 ng/ml) were achieved 1-2 days after treatment and maximum plasma concentrations of clorsulon (C_{max}: 2.58 µg/ml) were achieved approximately 8 hours after treatment.

Excretion: length of time and route

A dose rate of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight was administered by subcutaneous injection. For ivermectin, liver had the highest average residues, peaking on day 7 post dose at an average of 220 ppb. Depletion followed so that by days 28 and 35 the liver residues were 11 and 6 ppb respectively. Fat residues also peaked on day 7 at an average of 160 ppb. They decreased to 6 and 4 ppb by days 28 and 35 respectively. Muscle and kidney residues were negligible at 1 and 2 ppb respectively by day 28.

For clorsulon, kidney had the highest average residues of 0.54 ppm (540ppb) on day 3 post dose. At the same time, liver averaged 0.20 ppm, muscle averaged 0.06 ppm and fat averaged 0.02 ppm. Rapid depletion followed, resulting in average residues at or below the detection limit of 0.01 ppm by day 21 for all tissues.

In cattle receiving a single dose of tritium-labelled ivermectin (0.2-0.3 mg/kg bodyweight), analyses showed that composites of faeces collected during the first 7 days after dosing contained almost all the dosed radioactivity, only about 1-2% being excreted in the urine. Analyses of the faeces showed that about 40-50% of the excreted radioactivity was present as unaltered drug. The remaining 50-60% was present as metabolites or degradation products.

During the first 7 days following intra-ruminal administration of 7 mg/kg clorsulon to a 270 kg steer, about 90% of the radiolabel in the administered dose was found in the urine (25%) and the faeces (65%).

OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES), IF NECESSARY

The administration of 5 ml per 50 kg bodyweight (5 x the recommended dose rate.) resulted in injection site lesions (including swelling, sensitivity, oedema and inflammation). No other drug-related reactions have been observed.

INCOMPATIBILITIES

Do not mix with other medicinal products.

SHELF LIFE

Shelf-life of the veterinary medicinal product as packaged for safe: 3 years.

Shelf-life after first opening the immediate packaging: Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

SPECIAL PRECAUTIONS FOR STORAGE

Protect from light.

Keep the container in the outer carton in order to protect from light.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIAL, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the 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.

MARKETING AUTHORISATION HOLDER

Bimeda® Animal Health Limited

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Tel: +353 (0) 1 466 7900

LEGAL CATEGORY

LM

MARKETING AUTHORISATION NUMBER

VPA 22033/002/001

PACKAGE QUANTITIES

50ml, 250ml, 300ml, 500ml and 1250ml promo pack

TAKE TIME



OBSERVE LABEL DIRECTIONS

www.bimeda.ie

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