CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIMECTIN 1% w/v Solution for Injection
For the treatment and control of internal and external parasites of cattle, sheep and pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains Ivermectin 1% w/v in a non-aqueous solution.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50ml, 250ml, 500ml

5. TARGET SPECIES

Cattle, Sheep and Pigs

6. INDICATION(S)

Cattle: For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, mange mites and sucking lice of cattle.
Sheep: For the treatment and control of gastro-intestinal roundworms, lungworms and nasal bots of sheep.
Pigs: For the treatment and control of gastro-intestinal nematodes, lungworms, lice and mange mites of pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Method and route of administration:

Cattle: Dosage: 1 ml per 50 kg bodyweight (200 mcg ivermectin per kg bodyweight).
Administration: Inject subcutaneously in front or behind the shoulder using aseptic technique and a 17 gauge ½ inch needle.
Sheep: Dosage: 0.5 ml per 25 kg bodyweight (200 mcg ivermectin per kg bodyweight).
Administration: Inject subcutaneously over the neck using aseptic technique and a 17 gauge ½ inch needle
Pigs: Dosage: 1 ml per 33 kg bodyweight (300 mcg ivermectin per kg bodyweight).
Administration: Inject subcutaneously into the neck using aseptic technique and a 17 gauge ½ inch needle.

The volume administered per injection site should not exceed 10ml.

8. WITHDRAWAL PERIOD

Withdrawal periods:

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.

9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use.
This product does not contain an antimicrobial preservative.
Discard unused product safely.
Do not contaminate surface waters or ditches with product container or unused product.

For indications, contra-indications, warnings, precautions for use, disposal and further information: Read the package leaflet before use.

10. EXPIRY DATE

Shelf life after first opening the container: 28 days.
Once broached use by _____.
EXP:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

POM–VPS - Prescription Only Medicines – Veterinarian, Pharmacist and SQP

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4002

17. MANUFACTURER'S BATCH NUMBER

Date of manuf:
Batch:

LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIMECTIN 1% w/v Solution for Injection
For Cattle, Sheep and Pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains Ivermectin 1% w/v (10mg/ml) in a non-aqueous solution.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50ml, 250ml, 500ml

5. TARGET SPECIES

Cattle, Sheep and Pigs

6. INDICATION(S)

Cattle: For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, mange mites and sucking lice of cattle.
Sheep: For the treatment and control of gastro-intestinal roundworms, lungworms and nasal bots of sheep.
Pigs: For the treatment and control of gastro-intestinal nematodes, lungworms, lice and mange mites of pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Method and route of administration:

Cattle: 1 ml per 50 kg bodyweight (200 mcg Ivermectin per kg bodyweight). Inject subcutaneously in front or behind the shoulder.
Sheep: 0.5 ml per 25 kg bodyweight (200 mcg Ivermectin per kg bodyweight). Inject subcutaneously into the neck.
Pigs: 1 ml per 33 kg bodyweight (300 mcg Ivermectin per kg bodyweight) Inject subcutaneously into the neck.

The volume administered per injection site should not exceed 10ml

8. WITHDRAWAL PERIOD

Withdrawal Periods:

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.

9. SPECIAL WARNING(S), IF NECESSARY

For indications, contra-indications, warnings, precautions for use, disposal and further information: Read the package leaflet before use.

This product does not contain an antimicrobial preservative.
Extremely dangerous to fish and aquatic life.
Do not contaminate surface waters or ditches with product container or unused product.

10. EXPIRY DATE

Shelf life after first opening the container: 28 days.
Once broached use by _____.
EXP:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

POM–VPS - Prescription Only Medicines – Veterinarian, Pharmacist and SQP

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Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4002

17. MANUFACTURER’S BATCH NUMBER

Date of manuf:
Batch:

PACKAGE LEAFLET FOR: BIMECTIN 1% w/v Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND SITE OF BATCH RELEASE

Bimeda Animal Health Ltd,
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIMECTIN 1% w/v Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

A clear, colourless, slightly viscous, non-aqueous sterile solution containing 1% w/v ivermectin.

The product does not contain an antimicrobial preservative.

4. INDICATION(S)

Cattle:
For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, mange mites and sucking lice of cattle, as shown below.

The product at the recommended dosage level of 200 mcg ivermectin per Kg bodyweight:

1. Provides effective control against the following parasites of cattle.
   Gastro-intestinal worms (adult and fourth stage larvae): *Ostertagia* spp (including inhibited *O. ostertagi*), *Haemonochus placei, Trichostrongylus axei, Trichostrongylus 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.*
   Eyeworms (adult): *Thelazia* spp.
   Warbles (parasitic stages): *Hypoderma bovis* and *H. lineatum.*
   Mange mites: *Psoroptes bovis, Sarcoptes scabiei* var*. bovis.*
   Sucking lice: *Linognathus vituli, Haematopinus eurysternus* and *Solenopotes capillatus.*

2. May also be used as an aid in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur.
   When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment at the recommended dose rate controls re-infection with *Haemonchus placei*, and *Cooperia* spp. acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesphagostomum radiatum*

acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired 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 their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set stocked in the programme and that no untreated cattle are added to the pasture.
Treated calves should always be monitored according to good husbandry practices.

Sheep:
For the treatment and control of gastro-intestinal roundworms, lungworms and nasal bots of sheep.
The product, at the recommended dosage level of 200 mcg ivermectin per kg bodyweight, effectively controls the following parasites of sheep:
Gastrointestinal Roundworms (adult and fourth stage larvae): *Ostertagia circumcincta* (including inhibited fourth stage larvae), *O. trifurcata, Haemonchus contortus* (including inhibited fourth stage larvae), *Trichostrongylus colubriformis, Cooperia curticei, Oesphagostomum columbianum, Nematodirus filicollis, Chabertia ovina, Trichostrongylus. axei* (adult), *T. vitrinus* (adult), *Oesphagostomum venulosum* (adult), *Trichuris ovis* (adult).
Lungworms (adult and fourth stage): *Dictyocaulus filaria, Protostrongylus rufescens* (adult).
Nasal bots (adult immature): *Oestrus ovis* (includes somatic larval stages).

Pigs:
For the treatment and control of gastro-intestinal nematodes, lungworms, lice and mange mites of pigs.
The product at the recommended dose rate of 300 mcg ivermectin per kg bodyweight provides effective control against the following parasites of pigs:
Gastro-intestinal roundworms (adults and fourth stage larvae): *Ascaris suum, Hyostrongylus rubidus, Oesophagostomum* spp. and adult and somatic larval stages of *Strongyloides ransomi.*
Lungworms: *Metastrongylus* spp. (adults)
Lice: *Haematopinus suis.*
Mites: *Sarcoptes scabiei* var. *suis.*

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient.
This product is not for intravenous or intramuscular use.

6. ADVERSE REACTIONS

Cattle
Mild and 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.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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.

10 WITHDRAWAL PERIODS

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNINGS

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.

(i) **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.

(ii) **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.

(iii) Other precautions

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.

(iv) 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.

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

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 recumbancy.

In case of overdose, symptomatic treatment should be given.

(vi) Incompatibilities

Do not mix with other medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2019

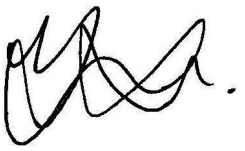
15. OTHER INFORMATION

Package quantities: 50 ml, 250 ml and 500 ml containers
Not all pack sizes may be marketed.

Legal Category: POM-VPS

Marketing Authorisation Number: Vm 50146/4002

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic endectocides.



Approved: 05 September 2019