PARTICULARS TO APPEAR ON THE OUTER PACKAGE – carton box, 1L, 2.5L and 5L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimeprine 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5.00 mg/ml

3. PACKAGE SIZE

1 L
2.5 L
5 L

4. TARGET SPECIES

Cattle (beef and dairy cattle).

5. INDICATIONS

For OTC products.
Treatment of infestations by eprinomectin sensitive strains of gastrointestinal roundworms, lungworms, warbles, mange mites, sucking lice, biting lice and horn flies.

6. ROUTES OF ADMINISTRATION

Pour-on use
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 15 days.
Milk: zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate container: 18 months and before expiry date.
Once broached, use by…

9. SPECIAL STORAGE PRECAUTIONS

1L: Keep the bottle in the outer carton in order to protect from light.
2.5L and 5L: This veterinary medicinal product does not require any special storage conditions.
Once opened the bottles must be kept upright.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Only for those countries where the product is available subject to prescription.
To be supplied only on veterinary prescription.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 50146/4007

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – label 1L, 2.5L and 5L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimeprine 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5.00 mg/ml

3. TARGET SPECIES

Cattle (beef and dairy cattle)

4. ROUTES OF ADMINISTRATION

Pour-on use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 15 days.
Milk: zero hours.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate container: 18 months and before expiry date.
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

1 L: Keep the bottle in the outer carton in order to protect from light.
2.5L and 5L This veterinary medicinal product does not require any special storage conditions.
Once opened the bottles must be kept upright.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE – carton box, 7L, 10L, 12.5L and 15L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimeprine 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5.00 mg/ml

3. PACKAGE SIZE

7.5L (3x2.5L)
10.0L (2x L)
12.5L (2x5L+1x2.5L)
15.0L (3x5L)

4. TARGET SPECIES

Cattle (beef and dairy cattle).

5. INDICATIONS

For OTC products.
Treatment of infestations by eprinomectin sensitive strains of gastrointestinal roundworms, lungworms, warbles, mange mites, sucking lice, biting lice and horn flies.

6. ROUTES OF ADMINISTRATION

Pour-on use
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 15 days.
Milk: zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate container: 18 months and before expiry date.
Once broached, use by…

9. SPECIAL STORAGE PRECAUTIONS

1L: Keep the bottle in the outer carton in order to protect from light.
2.5L and 5L: This veterinary medicinal product does not require any special storage conditions.
Once opened the bottles must be kept upright.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBER

Vm 50146/4007

15. BATCH NUMBER

Lot {number}

Other Information:

Company Logo

For combination packages including dosing gun the following statements will be included:

7.5L presentation:

"7.5L BIMEPRINE COMBI-PACK
3x2.5L Bimeprine
1x Dosing gun"

"Treats 125 x 600kg Cattle"

10L presentation:

“10L BIMEPRINE COMBI-PACK
2x5L Bimeprine
1x Dosing gun”

“Treats 166 x 600kg Cattle”

12.5L presentation:

“12.5L BIMEPRINE COMBI-PACK
2x5L Bimeprine
1x2.5L Bimeprine
1x Dosing gun”

“Treats 208 x 600kg Cattle”

15L presentation:

“15L BIMEPRINE COMBI-PACK
3x5L Bimeprine
1x Dosing gun”

“Treats 250 x 600kg Cattle”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bimeprine 5 mg/ml pour-on solution for cattle

2. Composition

One ml of solution contains:

Active substance:
Eprinomectin 5.00 mg

Excipients:
Butyl hydroxytoluene (E 321) 0.10 mg
All-rac-alpha-tocopherol (E 307) 0.06 mg

Pale yellow to yellow clear solution.

3. Target species

Cattle (beef and dairy cattle).

4. Indications for use

Treatment of infestations by the following parasites sensitive to eprinomectin:

PARASITE	ADULT	L4	Inhibited L4
Gastrointestinal roundworms			
Ostertagia ostertagi	♦	♦	♦
Ostertagia lyrata	♦		
Haemonchus placei	♦	♦	
Trichostrongylus axei	♦	♦	
Trichostrongylus colubriformis	♦	♦	
Cooperia spp.	♦	♦	♦
Cooperia oncophora	♦	♦	
Cooperia punctata	♦	♦	
Cooperia pectinata	♦	♦	
Cooperia surnabada	♦	♦	
Bunostomum phlebotomum	♦	♦	
Nematodirus helvetianus	♦	♦	
Oesophagostomum radiatum	♦	♦	
Oesophagostomum sp.	♦		
Trichuris discolor	♦		
Lungworms			
Dictyocaulus viviparus	♦	♦	

- Warbles (parasitic stages):
Hypoderma bovis
Hypoderma lineatum

- Mange mites:
Chorioptes bovis
Sarcoptes scabiei var. *Bovis*

- Sucking lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

- Biting lice:
Bovicola (Damalinia) bovis

- Horn flies:
Haematobia irritans

The product protects the animals against reinfestations with:
- *Nematodirus helvetianus* for 14 days.
- *Trichostrongylus axei* for 21 days.
- *Dictyocaulus viviparus, Haemonchus placei, Cooperia oncophora, Cooperia punctata, Cooperia surnabada, Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days.

The duration of persistent efficacy can be variable for *Cooperia spp* and *H. placei* 14 days after treatment in particular in young and lean animals at the time of treatment.

5. Contraindications

Avermectins may not be well tolerated in non-target species (including dogs, cats and horses). Cases of mortality are reported in dogs, especially Collies, bobtail and related breeds and crosses, and also in turtles/tortoises.
Do not use in other animal species.
Do not administer orally or by injection.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Care should be taken to avoid the following practices because they increase the risk of devel-opment 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 bodyweight, 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 ap-propriate 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 pharmaco-logical class and having a different mode of action should be used.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported in cattle within the EU. However, resistance to other macrocyclic lactones has been reported in parasite species in cattle within the EU. Therefore, 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.

If there is a risk for re- infection, the advice of a veterinarian should be sought regarding the need for and frequency of repeat administration.

For the best results the product should be part of a planned programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

Special precautions for safe use in the target species:

For external use only.
For effective use, the product should not be applied to areas of the backline covered with mud or manure.
The product should be applied only on healthy skin.
To avoid adverse reactions due to the death of warble larvae in the oesophagus or backbone, it is recommended to administer the product after the end of warble fly activity and before the larvae reach their resting sites in the body; consult a veterinary surgeon to know the appropriate treatment period.

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

This product may be irritating to the skin and eyes and may cause hypersensitivity (allergic reactions).
Avoid contact with the skin and eyes during treatment and when handling recently treated animals.
Wear rubber gloves, boots and a waterproof coat when applying the product.
If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water.
Should clothing become contaminated, remove as soon as possible and launder before re-use.
This product may affect the central nervous system if accidentally ingested. Avoid accidental ingestion of the product, including by hand to mouth contact. If ingestion does occur, wash the mouth out with water and seek medical advice.
Do not smoke, eat or drink while handling the product.
Wash hands after use.

Special precautions for the protection of the environment:

Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments. Faeces containing eprinomectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms.

Following treatment of cattle with the product, levels of eprinomectin that are potentially toxic to dung fly species may be excreted over a period of more than 4 weeks and may decrease dung fly abundance during that period. In case of repeated treatments with eprinomectin (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.
Eprinomectin is inherently toxic to aquatic organisms. The product should be used only according to the label instructions. Based on the excretion profile of eprinomectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first 7 days after treatment.

Pregnancy and lactation:

Laboratory studies (rat, rabbit) have not produced any evidence of a teratogenic or embryotoxic effects due to the use of eprinomectin at therapeutic doses. The safety of the veterinary medicinal product in cattle has been established during pregnancy and lactation and in reproductive bulls.
Can be used during pregnancy and lactation as well as in reproductive bulls.

Interaction with other medicinal products and other forms of interaction:

Since eprinomectin binds strongly to plasma proteins, this should be taken into account if it is used in association with other molecules having the same characteristics.

Overdose:

No signs of toxicity have been observed after administration of up to 5 times the recommended dose. No specific antidote has been identified.

Major incompatibilities:

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

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Licking at application site[1], Application site twitching[1], Application site reaction (e.g. application site skin scaling, application site squamosis)[2].

[1]Transient
[2]Minor

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Pour-on use.

To be administered topically in one single treatment at the dose rate of 500 µg eprinomectin per kg bodyweight equivalent to 1 ml per 10 kg bodyweight.

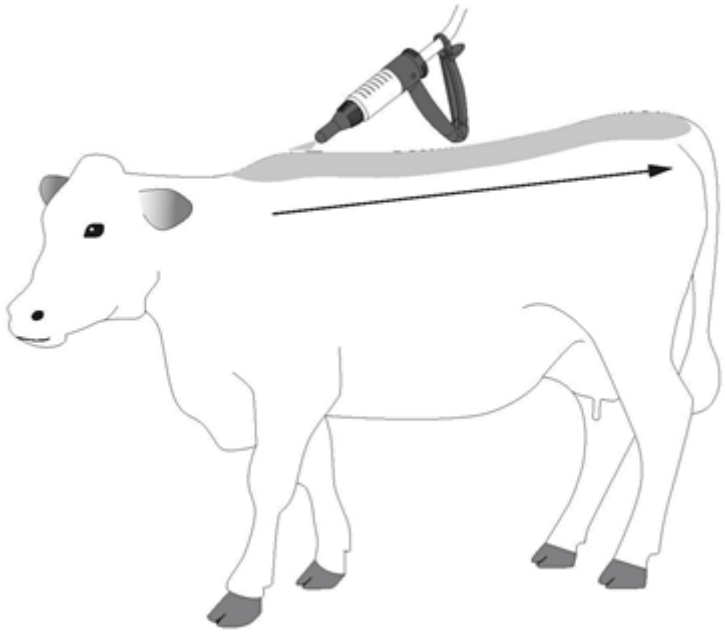
Apply the pour-on solution along the backline in a narrow strip extending from the withers to the tail head.

9. Advice on correct administration

All the animals belonging to the same group should be treated at the same time.

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

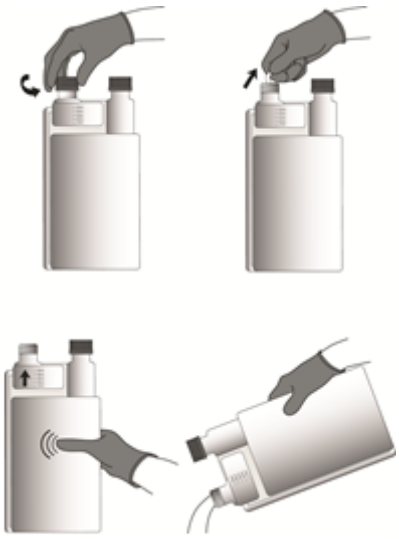
Method of Administration:



For the 1 litre presentation:
The bottle is equipped with an integrating dosing system, and has two openings. One opening is connected to the body of the container and the other one to the dispensing chamber (dosing system).

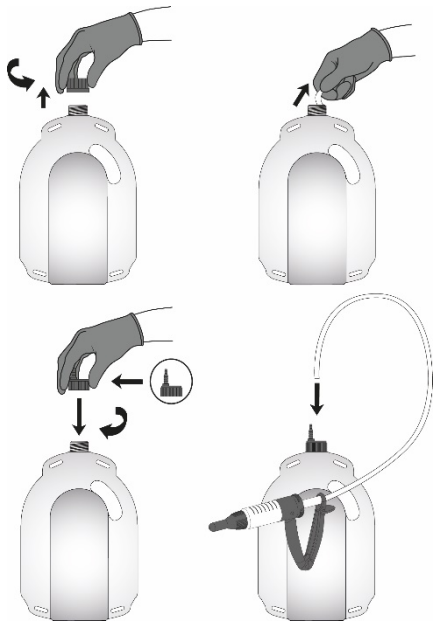
Unscrew the cap and remove the seal of the dispensing chamber (integrated dosing system allowing 10-ml doses and 50-ml doses).
Squeeze the bottle to fill the dispensing chamber with the required volume of product.

Figure1 Use of the graduated chamber on the 1litre containers:



<u>For the 2.5 L and 5 L presentations:</u>
To be used with an appropriate dosing system such as a dosing gun and coupling vented cap.
Unscrew the polypropylene (PP) simple cap. Remove the protective seal from the bottle. Screw the coupling vented cap on the bottle and make sure it is tightened. Connect the other side to a dosing gun.
Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun.
After use, coupling vented caps should be removed and replaced by PP simple cap.
Vented caps should be placed for a later use in the cardboard box.

Figure 2 Attaching the recommended dosing gun to the 2.5 and 5 litre containers:



10. Withdrawal periods

Meat and offal: 15 days.
Milk: zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

1.0L Keep the bottle in the outer carton in order to protect from light.
2.5L and 5.0L This veterinary medicinal product does not require any special storage conditions.
Once opened the bottles have to be kept upright.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 18 months and before expiry date.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product is dangerous for fish and aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50146/4007

Pack sizes:
Box of 1L bottle
Box of 2.5L bottle
Box of 5L bottle

Box of 7.5L (3x2.5L+dosing gun)
Box of 10.0L (2x5L + dosing gun)
Box of 12.5L (2x5L +1x 2.5L + dosing gun)
Box of 15.0L (3x5L + dosing gun).

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

Manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona) Spain

Local representatives and contact details to report suspected adverse reactions:
Cross Vetpharm Group UK Limited (Trading as Bimeda)
Unit 2, Bryn Cefni Industrial Park
Llangefni, LL77 7XA
United Kingdom
Tel: 01248 725 400

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 18 August 2025