[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimepro 5 mg/ml pour-on solution for cattle [FR]
Nullamec 5 mg/ml pour-on solution for cattle [IE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains:

Active substance:
Eprinomectin 5.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E 321)	0.10 mg
All-rac-alpha-tocopherol (E 307)	0.06 mg
Propylene glycol dicaprylocaprate	

Pale yellow to yellow clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and dairy cattle).

3.2 Indications for use for each target species

Treatment of infestations by the following parasites:

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.

3.3 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.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal or herd.

For effective use, the veterinary medicinal product should not be applied to areas of the backline covered with mud or manure.

The veterinary medicinal product should be applied only on healthy skin.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (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.

In order to limit cross-transfer of eprinomectin, treated animals should preferably be separated from untreated animals. Non-compliance with this recommendation may lead to residue violations in untreated animals and development of resistance to eprinomectin.

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 reinfection, 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.

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:
For external use only.
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.
People with known hypersensitivity to eprinomectin should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of rubber gloves, boots and a waterproof coat should be worn when handling the veterinary medicinal 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 veterinary medicinal 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.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction (Licking at application site, application site irritation, application site dry skin, application site skin scaling)*

*Transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

Fertility:
The safety of the veterinary medicinal product in cattle has been established in reproductive bulls.

3.8 Interaction with other medicinal products and other forms of interaction

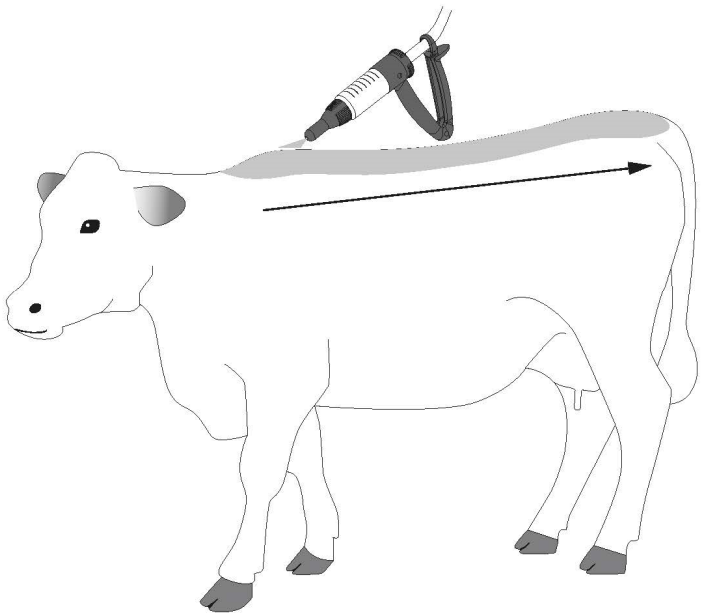
Since eprinomectin binds strongly to plasma proteins, this should be taken into account if it is used in association with other molecules having the same characteristics.

3.9 Administration routes and dosage

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.



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

Underdosing could result in ineffective use and may favour resistance development.

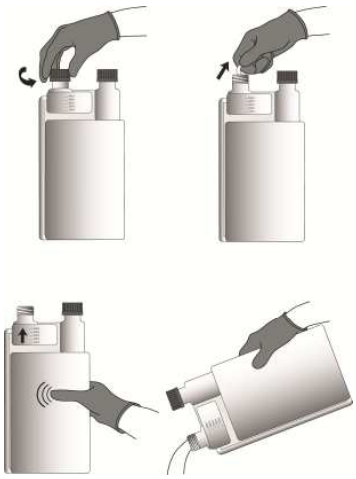
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Accuracy of the dosing device should be thoroughly checked.

Method of Administration:

<u>For the 1 litre presentation:</u>
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.

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



For the 2.5 L and 5 L presentations:
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:

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA04.

4.2 Pharmacodynamics

Eprinomectin is a molecule with an endectocidal activity belonging to the macrocyclic lactone class. Compounds of the class bind with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve or muscle cells. These compounds bind selectively to these channels, which 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 GABA (gamma-aminobutyric acid).

4.3 Pharmacokinetics

The bioavailability of topically applied eprinomectin in cattle is about 30% with most absorption occurring by about 10 days after treatment. Eprinomectin is strongly linked to plasma proteins (99%). Eprinomectin is not extensively metabolized in cattle following topical administration.
Faeces are the major route of elimination.

Environmental properties
Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms (See section 3.5 Special precautions for the protection of the environment).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 18 months and before expiry date.

5.3. Special precautions for storage

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

5.4 Nature and composition of immediate packaging

- Squeeze-measure pour-on system:
1 L natural high density polyethylene (HDPE) bottle with integrated measuring chamber graduated each 10 ml up to 50 ml, removable aluminium/PE seals and HDPE screw cap included in a cardboard box.
- Back pack:
2.5 L and 5 L white HDPE bottles with a removable (ethylene-methacrylic acid) zinc co-polymer seal, a polypropylene (PP) screw cap and a PP coupling vented cap included in a cardboard box.

Pack sizes: 1L, 2.5L, 5L, 7.5L (3x2.5L), 10.0L (2x5L) and 12.5L (2x5L+1x2.5L).

Box of 1L bottle.
Box of 2.5L bottle.
Box of 5L bottle.

Box of 7.5L (3x2.5L), package contains three 2.5L presentation and a pour on dosing gun.
Box of 10L (2x5L) package contains two 5L presentation and a pour on dosing gun.
Box of 12.5L (2x5L+1x2.5L), package contains two 5L presentation, one 2,5L presentation and a pour on dosing gun.

The dosing gun includes PVC tubing and a plastic dosing chamber.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON : 1 L, 2.5 L and 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimepro 5 mg/ml pour-on solution [FR]
Nullamec 5 mg/ml pour-on solution [IE]

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

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 18 months and before expiry date.

9. SPECIAL STORAGE PRECAUTIONS

1 L: Keep the bottle in the outer carton in order to protect from light.
2.5 L and 5 L: This veterinary medicinal product does not require any special storage conditions.
Once opened, keep the container 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.

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

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL : 1 L, 2.5 L and 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimepro 5 mg/ml pour-on solution [FR]
Nullamec 5 mg/ml pour-on solution [IE]

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

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 18 months and before expiry date.

7. SPECIAL STORAGE PRECAUTIONS

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

Once opened, keep the container 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 : 7.5 L, 10.0 L and 12.5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimepro 5 mg/ml pour-on solution [FR]
Nullamec 5 mg/ml pour-on solution [IE]

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5.00 mg/ml

3. PACKAGE SIZE

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

7.5L BIMEPRO® COMBI- PACK
3x2.5L Bimepro®
1x Dosing gun

Treats 125 x 600kg Cattle

7.5L NULLAMEC® COMBI- PACK
3x2.5L Nullamec®
1x Dosing gun

Treats 125 x 600kg Cattle

10L BIMEPRO® COMBI- PACK
2x5L Bimepro®
1x Dosing gun

10L NULLAMEC® COMBI- PACK
2x5L Nullamec®
1x Dosing gun

Treats 166 x 600kg Cattle

12.5L BIMEPRO® COMBI- PACK
2x5L Bimepro®
1x2.5L Bimepro®
1x Dosing gun

12.5L NULLAMEC® COMBI- PACK
2x5L Nullamec®
1x2.5L Nullamec®

1x Dosing gun

Treats 208 x 600kg Cattle

4. TARGET SPECIES

Cattle (beef and dairy cattle).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 18 months and before expiry date.

9. SPECIAL STORAGE PRECAUTIONS

1 L: Keep the bottle in the outer carton in order to protect from light.
2.5 L and 5 L: This veterinary medicinal product does not require any special storage conditions.
Once opened, keep the container 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.

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

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bimepro 5 mg/ml pour-on solution for cattle [FR]
Nullamec 5 mg/ml pour-on solution for cattle [IE]

2. Composition

One ml of solution contains:

Active substance:
Eprinomectin 5.00 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:

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:
Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal or herd.

For effective use, the veterinary medicinal product should not be applied to areas of the backline covered with mud or manure.

The veterinary medicinal product should be applied only on healthy skin.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to

reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (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.

In order to limit cross-transfer of eprinomectin, treated animals should preferably be separated from untreated animals. Non-compliance with this recommendation may lead to residue violations in untreated animals and development of resistance to eprinomectin.

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 reinfection, 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.

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Special precautions for safe use in the target species:
For external use only.
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.
People with known hypersensitivity to eprinomectin should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of rubber gloves, boots and a waterproof coat should be worn when handling the veterinary medicinal 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 veterinary medicinal 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.

Fertility:
The safety of the veterinary medicinal product in cattle has been established 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):	Application site reaction (Licking at application site, application site irritation, application site dry skin, application site skin scaling)*

*Transient.

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 using the contact details at the end of this leaflet, or via your national reporting system:

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

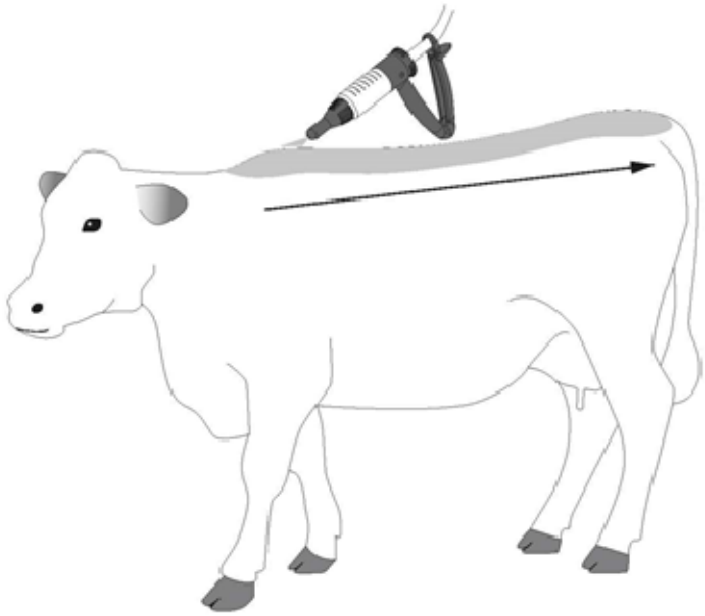
All the animals belonging to the same group should be treated at the same time.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

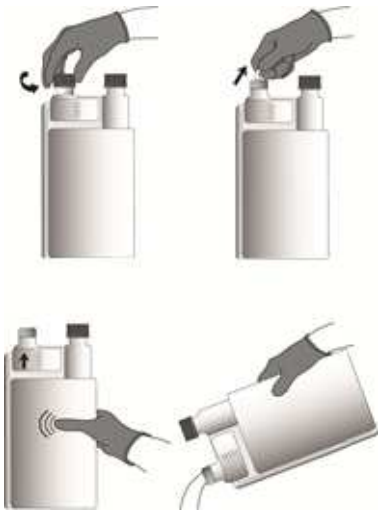
Accuracy of the dosing device should be thoroughly checked.

Method of Administration:



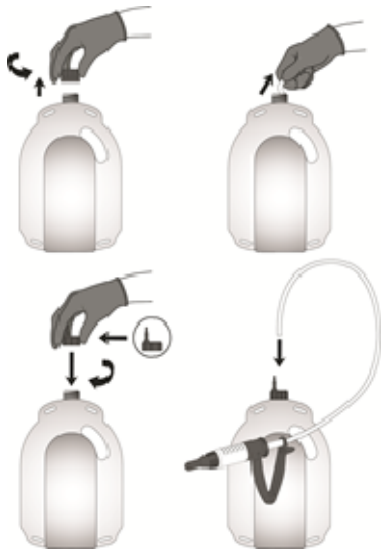
For the 1 litre presentation:
The bottle is equipped with an integrating dosing system and has two openings. One opening is connected to the body of the container and the other one to the dispensing chamber (dosing system).
Unscrew the cap and remove the seal of the dispensing chamber (integrated dosing system allowing 10-ml doses and 50-ml doses).
Squeeze the bottle to fill the dispensing chamber with the required volume of product.

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



For the 2.5 L and 5 L presentations:
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.

This veterinary medicinal product is dangerous for fish and aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Cardboard box with 1 L bottle
Cardboard box with 2.5 L bottle
Cardboard box with 5 L bottle

Cardboard box with 7.5 L (3 x 2.5 L bottles + dosing gun)
Cardboard box with 10.0 L (2 x 5 L bottles + dosing gun)
Cardboard box with 12.5 L (2 x 5 L + 1 x 2.5 L bottles + dosing gun)

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Bimeda Animal Health Ltd.
2, 3 & 4 Airton Close,
Tallaght, Dublin 24,
Ireland.
Tel: +353 1 4667900

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