1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zeromectin 5 mg/ml Pour-on Solution for beef and dairy cattle (IE)
Epricert 5 mg/ml Pour-on Solution for beef and dairy cattle (UK(NI))
Ecuprec 5 mg/ml Pour-on Solution for beef and dairy cattle (IT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each ml contains:

Eprinomectin 5 mg.

Excipients:

Each ml contains:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylated hydroxytoluene (E321)	10 mg
Propylene glycol dicaprylocaprate	

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 internal and external parasites sensitive to eprinomectin:

Gastrointestinal roundworms (adults and fourth-stage larvae)
Ostertagia spp.
*Ostertagia lyrata (*adults only).
Ostertagia ostertagi (including inhibited L4).
Cooperia spp. (including inhibited L4).
Cooperia oncophora.
Cooperia pectinate.
Cooperia punctate.
Cooperia surnabada.
Haemonchus placei.
Trichostrongylus spp.
Trichostrongylus axei.
Trichostrongylus colubriformis.
Bunostomun phlebotomum.
Nematodirus helvetianus.

Oesophagostomum spp. (adults only).
Oesophagostomum radiatum.
Trichuris spp. (adults only).

Lungworms
Dictyocaulus viviparus (adults and L4).

Warbles (parasitic stages)
Hypoderma bovis.
Hypoderma lineatum.

Mange Mites
Chorioptes bovis.
Sarcoptes scabiei var.*bovis.*

Lice
*Damalinia (Bovicola) bovis (*biting lice).
Linognathus vituli (sucking lice).
Haematopinus eurysternus (sucking lice).
Solenopotes capillatus (sucking lice).

Horn flies
Haematobia irritans.

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

3.3 Contraindications

The product is formulated only for topical application for beef and dairy cattle, including lactating dairy cattle.
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

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 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 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.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported 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 programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

3.5 Special precautions for use

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 regarding the appropriate time for treatment.
Rainfall at any time before or after treatment will not affect the efficacy of the product.

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

This product may be irritating to human skin and eyes and may cause hypersensitivity.
Avoid direct contact with the skin or eyes.
Wear rubber gloves and protective clothing when applying the product.
If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water.
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use. Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.
People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Eprinomectin is very toxic to dung fauna and aquatic organisms, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of eprinomectin (and products of the same anthelmintic class) in cattle.

The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for three weeks after treatment.

Other precautions:

Not to be used in other species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

3.6 Adverse events

Cattle (beef and dairy cattle)

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site alopecia. Application site pruritus.

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 its local representative 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, lactation and fertility:
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 eprinomectin 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.

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.

Administer only by topical application at the dose rate of 1 ml of the product per 10 kg of body weight, corresponding to the recommended dose rate of 0.5 mg eprinomectin per kg b.w. The product should be applied along the backline in a narrow strip extending from the withers to the tailhead.

To ensure a correct dosage, 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- and overdosing.

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

Method of administration:

For the 1 L presentation:
The bottle is equipped with an integrated dosing system and has two openings. One opening is connected to the body of the container and the other to the dispensing chamber (dosing system). Unscrew the tamper-evident cap and remove the seal of the dispensing chamber (integrated dosing system allowing 5 ml to 25 ml doses). Squeeze the bottle to fill the dispensing chamber with the required volume of product.

For the 2.5 L, 3 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 cap. Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun and vented cap. After use, coupling vented caps should be removed and replaced by the polypropylene cap.

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

No signs of toxicity appeared when 8-week-old calves were treated at up to 5x the therapeutic dose (2.5 mg Eprinomectin/kg b.w.) 3 times at 7-day intervals.
One calf treated once at 10x the therapeutic dose (5 mg/kg b.w.) in the tolerance study showed transient mydriasis. There were no other adverse reactions to treatment.
No 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 member of the macrocyclic lactone class of endectocides. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve or 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.

4.3 Pharmacokinetics

Metabolism
The bioavailability of topically applied eprinomectin in cattle is about 30% with most absorption occurring by about 10 days after treatment. Eprinomectin is not extensively metabolized in cattle following topical administration. In all biological matrices, the B1a component of eprinomectin is the single most abundant residue.

The contribution of eprinomectin B1a to the total radioresidue level remained relatively constant between 7 days and 28 days after treatment - for example, between 84% and 90% in liver, the proposed principal target tissue.

Maximum plasma concentration
In beef cattle treated topically with radiolabelled eprinomectin at the recommended dose of 0.5 mg/kg bodyweight, there was no distinct peak in the plasma radioactivity versus time curve, but a broad plateau

occurred between 9 and 14 days after dosing. Highest concentrations of eprinomectin B1a were in the range of 7.33 - 19.74 ng/ml.
In lactating dairy cows treated topically with 0.75 mg radiolabelled eprinomectin/kg bodyweight, some animals showed a distinct peak in plasma radioactivity levels, whereas others exhibited a broad plateau. Peak levels of eprinomectin B1a were in the range of 42.7 - 134.4 ng/ml. The highest levels of plasma radioactivity occurred between one and 7 days after dosing.

Excretion
Faeces was the major route of elimination of the drug in beef cattle and dairy cows.
In beef cattle, faeces and urine were collected from 2 steers, and the amount of drug excreted up to 28 days after dosing was determined as 15 – 17 % and 0.25 % in faeces and urine, respectively. A further 53 – 56 % of the dose was recovered from the skin at the application site collected from 3 animals sacrificed at 28 days after dosing.

Environmental properties

Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of eprinomectin may take place over a period of several weeks. Faeces containing eprinomectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation. Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments.

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: 36 months.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

For Squeeze pour containers (1 L): Keep the container in the outer container in order to protect from light.

For Flexi-pack containers (2.5 L, 3 L and 5 L): Protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene container with a polypropylene tamper evident screw cap which consists of the following:
1L ‘Squeeze pour’ packs.
2.5 L, 3 L and 5 L ‘Flexi’ packs.
Pack sizes 1 L, 2.5 L, 3 L and 5 L.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 should not enter watercourses as eprinomectin may be extremely dangerous for fish and other aquatic organisms.

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

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}><{DD month YYYY}>

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

<{MM/YYYY}>

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 (1L, 2.5L, 3L & 5L)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zeromectin 5 mg/ml Pour-On Solution (IE)
Epricert 5 mg/ml Pour-on Solution (UK(NI))
Ecuprec 5 mg/ml Pour-on Solution (IT)

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin: 5 mg/ml.

3. PACKAGE SIZE

1 L, 2.5 L, 3 L & 5 L.

4. TARGET SPECIES

Cattle (beef and dairy cattle).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and Offal: 15 days.
Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

For Squeeze pour containers (1L): Keep the container in the outer container in order to protect from light.

For Flexi-pack containers (2.5 L, 3 L and 5L): Protect from light.

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

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Combined label and package leaflet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zeromectin 5 mg/ml Pour-On Solution For Beef and Dairy Cattle (IE)
Epricert 5 mg/ml Pour-on Solution for beef and dairy cattle (UK(NI))
Ecuprec 5 mg/ml Pour-on Solution for beef and dairy cattle (IT)

2. COMPOSITION

Clear solution.

Active substance:

Each ml contains:

Eprinomectin 5 mg

Excipients:

Each ml contains:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylated hydroxytoluene (E321)	10 mg
Propylene glycol dicaprylocaprate	

3. PACKAGE SIZE

1 L, 2.5 L, 3 L & 5 L

4. TARGET SPECIES

Cattle (beef and dairy cattle).

5. INDICATIONS FOR USE

Indications for use

Treatment of infestations by the following internal and external parasites sensitive to eprinomectin:

Gastrointestinal roundworms (adults and fourth-stage larvae)
Ostertagia spp.
*Ostertagia lyrata (*adults only)
Ostertagia ostertagi (including inhibited L4)
Cooperia spp. (including inhibited L4)
Cooperia oncophora

Cooperia pectinata
Cooperia punctata
Cooperia surnabada
Haemonchus placei
Trichostrongylus spp.
Trichostrongylus axei
Trichostrongylus colubriformis
Bunostomun phlebotomum
Nematodirus helvetianus
Oesophagostomum spp. (adults only)
Oesophagostomum radiatum
Trichuris spp. (adults only)

Lungworms
Dictyocaulus viviparus (adults and L4)

Warbles (parasitic stages)
Hypoderma bovis
Hypoderma lineatum

Mange Mites
Chorioptes bovis
Sarcoptes scabiei var.*bovis*

Lice
*Damalinia (Bovicola) bovis (*biting lice)
Linognathus vituli (sucking lice)
Haematopinus eurysternus (sucking lice)
Solenopotes capillatus (sucking lice)

Horn flies
Haematobia irritans

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

6. CONTRAINDICATIONS

Contraindications

The product is only formulated for topical application for beef and dairy cattle, including lactating dairy cattle. 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.

7. SPECIAL WARNINGS

Special warnings

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 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 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.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported 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 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 regarding the appropriate time for treatment.
Rainfall at any time before or after treatment will not affect the efficacy of the product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may be irritating to human skin and eyes and may cause hypersensitivity.
Avoid direct contact with the skin or eyes.
Wear rubber gloves and protective clothing when applying the product.
If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water.
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use. Should clothing become contaminated, remove as soon as possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice.
People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
Eprinomectin is very toxic to dung fauna and aquatic organisms, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of eprinomectin (and products of the same anthelmintic class) in cattle.

The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for three weeks after treatment.

Other precautions:
Not to be used in other species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

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 eprinomectin 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.

Interactions 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 appeared when 8-week old calves were treated at up to 5x the therapeutic dose (2.5 mg Eprinomectin/kg b.w.) 3 times at 7-day intervals.
One calf treated once at 10x the therapeutic dose (5 mg/kg b.w.) in the tolerance study showed transient mydriasis. There were no other adverse reactions to treatment.
No 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.

8. ADVERSE EVENTS

Adverse events

Cattle (beef and dairy cattle)

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site alopecia. Application site pruritus.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 on this label, or via your national reporting system: {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Pour-on use.

Administer only by topical application at the dose rate of 1 ml of the product per 10 kg of body weight, corresponding to the recommended dose rate of 0.5 mg eprinomectin per kg b.w. The product should be applied along the backline in a narrow strip extending from the withers to the tailhead.

Rainfall before or after treatment will not affect the efficacy of the product.
All the animals belonging to the same group should be treated at the same time.

Body weight (kg)	Dose Volume (ml)	Doses per 1 Litre Pack	Doses per 2.5 Litre Pack	Doses per 3 Litre Pack	Doses per 5 Litre Pack
Up to 100	10	100	250	300	500
101 – 150	15	66	166	198	333
151 – 200	20	50	125	150	250
201 – 250	25	40	100	120	200
251 – 300	30	33	83	100	166

Over 300 kg bodyweight, give 5 ml per 50 kg bodyweight.

Method of administration:

For the 1 L presentation:
The bottle is equipped with an integrated dosing system and has two openings. One opening is connected to the body of the container and the other to the dispensing chamber (dosing system). Unscrew the tamper-evident cap and remove the seal of the dispensing chamber (integrated dosing system allowing 5 ml to 25 ml doses). Squeeze the bottle to fill the dispensing chamber with the required volume of product.

For the 2.5 L, 3 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 cap. Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun and vented cap. After use, coupling vented caps should be removed and replaced by the polypropylene cap.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, 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- and overdosing.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and Offal: 15 days.
Milk: Zero hours.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
Discard 6 months after first opening.

For Squeeze pour containers (1 L): Keep the container in the outer container in order to protect from light.
For Flexi-pack containers (2.5 L, 3 L and 5 L): Protect from light.

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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

This veterinary medicinal product should not enter watercourses as eprinomectin may be extremely dangerous for fish and other aquatic organisms. Do not contaminate lakes or waterways with the product or used containers.

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes: 1 L, 2.5 L, 3 L and 5 L
1 L ‘Squeeze pour’ packs.
2.5 L, 3 L and 5 L ‘Flexi’ packs.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

Local representatives and contact details to report suspected adverse reactions:

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

18. OTHER INFORMATION

Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of eprinomectin may take place over a period of several weeks. Faeces containing eprinomectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation. Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 6 months.

21. BATCH NUMBER

Lot {number}