A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epricert 5 mg/ml Pour-on Solution for beef and dairy cattle

Eprinomectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear pour-on solution.
1 ml contains: Eprinomectin 5 mg/ml
Butylated hydroxytoluene (E321) 10 mg

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1L, 2.5L, 3L & 5L

5. TARGET SPECIES

Cattle (beef and dairy cattle).

6. INDICATION(S)

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.

Approved for use in dairy cattle.
Controls roundworms, lungworms, warbles, mange mites, lice, horn flies

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.

Dosage: 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 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- and overdosing.

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 5ml per 50 kg bodyweight
Method of administration:

For the 1L 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 should be removed and replaced by the polypropylene cap.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and Offal: 15 days
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications:
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

Special precautions for use in animals
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.
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.

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 or eat 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 warnings for each target species
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of 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 each parasite.

<u>Use during pregnancy and lactation</u>
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.

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 (symptoms, emergency procedures, antidotes), if necessary
No signs of toxicity appeared when 8-week old calves were treated at up to 5 times the therapeutic dose (2.5 mg Eprinomectin/kg body weight) 3 times at 7-day intervals. One calf treated once at 10 times the therapeutic dose (5 mg/kg body weight) in the tolerance study showed transient mydriasis. There were no other adverse reactions to treatment.
No antidote has been identified.

Other precautions
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.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. Shelf life after first opening of the container: …"
Discard 6 months after first opening.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Extremely dangerous to fish and aquatic life. Do not contaminate lakes or waterways with the product or used containers.

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

For animal treatment only.
LM Licensed Merchant *(IE only, legal category to be added for each country as required)*

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/4060

17. MANUFACTURER'S BATCH NUMBER

BN:

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Label

1. NAME AND ADDRESS OF THE MARKETING AUTHORSATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epricert 5 mg/ml Pour-on Solution for beef and dairy cattle

Eprinomectin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

A clear pour-on solution.
One ml contains: Eprinomectin 5mg
Butylated hydroxytoluene (E321) 10 mg

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Mange Mites
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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.

Approved for use in dairy cattle.
Controls roundworms, lungworms, warbles, mange mites, lice, horn flies

5. CONTRAINDICATIONS

Do not use in other animal species; avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.
Do not administer orally or by injection.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients

6. ADVERSE REACTIONS

Pruritus and alopecia have been observed after the use of the veterinary medicinal product in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {*national system details*}.

7. TARGET SPECIES

Cattle (Beef and dairy cattle)

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

Pour-on use.

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

9. ADVICE ON CORRECT ADMINISTRATION

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- and overdosing.
The product should be used with appropriate dosing equipment.

10. WITHDRAWAL PERIOD

Meat and Offal: 15 days
Milk: Zero hours

11. SPECIAL STORAGE CONDITIONS

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For animal treatment only.

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

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Extremely dangerous to fish and aquatic life. Do not contaminate lakes or waterways with the product or used containers.

14. DATE ON WHICH THE LABEL WAS LAST APPROVED

July 2020

15. OTHER INFORMATION

BN:
EXP:

MA number to be inserted

1L, 2.5L, 3L and 5L.
Not all pack sizes may be marketed.

Approved: 19 August 2020