ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX 1 L, 2.5 L and 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Elivec 5 mg/ml pour-on solution for cattle
Eprinomectin

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5.00 mg/ml

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1 l
2.5 l
5 l

5. TARGET SPECIES

Cattle (beef and dairy cattle).

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

1 L: Keep the bottle in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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

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

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Livisto Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4006

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 1 L, 2.5 L and 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Elivec 5 mg/ml pour-on solution for cattle
Eprinomectin

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5.00 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1 l
2.5 l
5 l

5. TARGET SPECIES

Cattle (beef and dairy cattle)

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

1 L: Keep the bottle in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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

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

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Livisto Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4006

17. MANUFACTURER'S BATCH NUMBER

Batch:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Elivec 5 mg/ml pour-on solution for cattle

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

Marketing authorisation holder:
Livisto Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona)
Spain

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Elivec 5 mg/ml pour-on solution for cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One ml of solution contains:

Active substance:
Eprinomectin 5.00 mg

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

Pale yellow to yellow clear solution.

4. INDICATION(S)

Treatment of infestations by the following parasites sensitive to eprinomectin:

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

- 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. ADVERSE REACTIONS

In very rare cases, transient licking reactions, skin tremor at the administration site, minor local reactions such as the occurrence of dandruff and skin scales at the administration site have been observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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.

7. TARGET SPECIES

Cattle (beef and dairy cattle).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 graduated each 10 ml up to 50 ml).
Squeeze the bottle to fill the dispensing chamber with the required volume of product.

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 box.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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.
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 WARNING(S)

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 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 programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

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.

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 product.
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.

Other precautions
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.

Use during pregnancy, lactation or lay
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 (symptoms, emergency procedures, antidotes):
No signs of toxicity have been observed after administration of up to 5 times the recommended dose. No specific antidote has been identified.

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

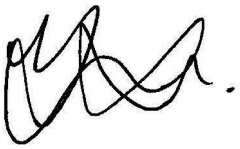
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

The veterinary medicinal product is dangerous for fish and aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
Box of 1L bottle
Box of 2.5L bottle
Box of 5L bottle
Not all pack sizes may be marketed.



Approved: 25 July 2022