ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EpriMole 5mg/ml pour-on solution for cattle
eprinomectin

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5 mg/ml

3. PHARMACEUTICAL FORM

Pour on solution.

4. PACKAGE SIZE

250 ml
1L
2.5L
5L

5. TARGET SPECIES

Cattle (beef and dairy cattle)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 15 days
Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
For external use only.

This product may be irritating to skin and eyes and may cause hypersensitivity.

Users should wear rubber gloves, boots and 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 eyes immediately with water.
See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by the expiry date.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

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

Extremely dangerous to fish and aquatic life. Do not contaminate lakes or waterways with the product or used containers. Disposal: read the package leaflet.

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

For animal treatment only.
[For products subject to veterinary 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

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4281

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 ml, 1L HDPE bottle / 2,5 L, 5 L HDPE back-pack.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

eprinomectin 5mg/ml

3. PHARMACEUTICAL FORM

Pour on solution

4. PACKAGE SIZE

250 ml
1L
2.5L
5L

5. TARGET SPECIES

Cattle (beef and dairy cattle)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 15 days.
Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
For full user warnings, see package leaflet.

10. EXPIRY DATE

EXP {month/year}
Once opened use by the expiry date.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

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

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

For animal treatment only.
[For products subject to veterinary 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

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4281

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Eprimole 5mg/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:
Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet- 31000 TOULOUSE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each ml contains:
Active substance:
Eprinomectin 5.0 mg
…….

Excipients:
Butylhydroxytoluene (E321) 0.1 mg
……

Clear slightly yellow solution.

4. INDICATIONS

Treatment of infestation by the following parasites sensitive to eprinomectin. It is indicated for parasite control in cattle, including lactating dairy cows.
Gastrointestinal Roundworms:
Inhibited L4 and L4 larvae, adult forms of *Ostertagia ostertagi*, *Cooperia* spp.
L4 larvae and adult forms of *Ostertagia spp.*, *C. oncophora*, *C. pectinata*, *C. punctata*, *C.surnabada*, *Haemonchus placei*, *Trichostrongylus* spp.,*T. axei*, *T. colubriformis*, *Bunostomum phlebotomum*, *O. radiatum*, *Nematodirus helvetianus*.
Adult forms of *O. lyrata*, *Oesophagostomum* spp*. Trichuris* spp*.*
Lungworm:
L4 larvae and adult forms of *Dictyocaulus viviparus*

Warbles:
Parasitic stages of *Hypoderma bovis*, *Hypoderma lineatum*,
Mange mites, *Chorioptes bovis*, *Sarcoptes scabiei var. bovis*,
Lice:
Linognathus vituli, *Haematopinus eurysternus*, *Damalinia bovis*, *Solenopotes capillatus*.

- **Prolonged activity:** Control of further infestation for up to :

-28 days for *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Ostertagia lyrata*, *Oesophagostomum radiatum*,
-21 days for *Cooperia oncophora*, *Cooperia surnabada*, *Cooperia punctata*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*
-14 days for *Haemonchus placei*, *Nematodirus helvetianus*

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

5. CONTRAINDICATIONS

This product is formulated only for topical application to 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.

6. ADVERSE REACTIONS

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

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.

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. For single administration only.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; 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 over- dosing. All the animals belonging to the same group should be treated at the same time.

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

9. ADVICE ON CORRECT ADMINISTRATION

For external use only.
For 250 ml and 1 liter bottles:

- Attach the dose dispenser to the bottle.
- Set the dose by turning the top section of the dose dispenser to align the correct bodyweight with the pointer inside the dose dispenser. When bodyweight is between markings, use the higher setting.
- Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.
- By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. For the 1 litre bottle: when a 10 ml or 15 ml dose is required, turn the pointer to “STOP” before delivering the dose. The off (STOP) position will close the system between dosing.
- The dose dispenser should not be stored attached to the bottle when not in use. Remove the dose dispenser after each use and replace with the bottle cap.

For 2.5 and 5 litre back-packs:
Connect the dosing gun and draw-off tubing to the back-pack as follows:

- Attach the open end of the draw-off tubing to an appropriate dosing gun.
- Attach draw-off tubing to the cap with the stem that is included in the pack. Replace shipping cap with the cap having the draw-off tubing. Tighten the draw-off cap.
- Gently prime the dosing gun, checking for leaks.
- Follow the dosing gun manufacturer’s directions for adjusting the dose and proper use and maintenance of the dosing gun and draw-off tubing.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the container in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: see expiry date.

12. SPECIAL WARNING(S)

Special warnings for each target species
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 secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites.

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.

While mite and louse numbers decline rapidly following treatment, due to the feeding habits of the parasites, in some cases several weeks may be required for complete eradication.

Special precautions for use in animals:
Do not use in other animal species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

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

- This product may be irritating to skin and eyes and may cause hypersensitivity.
- Avoid skin and eye contact with the product during treatment and when handling recently treated animals.
- Individuals with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the product.

- Users should wear rubber gloves, boots and a waterproof coat when applying the product.
- If accidental eye exposure occurs, flush eyes immediately with water and seek medical advice if irritation persists.
- If accidental skin contact occurs, wash the affected area immediately with soap and water.
- Should clothing become contaminated, remove as soon as possible and launder before re-use.
- This product may be toxic after accidental ingestion. Avoid accidental ingestion of the product by hand to mouth contact.
- Do not smoke, eat or drink while handling the product.
- In the event of ingestion, wash out mouth with water and seek medical advice.
- Wash hands after use.

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 two to five weeks after treatment.

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.

Pregnancy:
Can be used during pregnancy.
Studies have demonstrated a wide safety margin. Studies conducted at three times the recommended use level of 0.5 mg eprinomectin/kg b.w. had no adverse effect on breeding performance of cows or bulls.

Lactation:
May be used in dairy cattle during all stages of lactation.

Overdose (symptoms, emergency procedures, 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 the treatment.

No 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

Extremely dangerous to fish and aquatic life. Do not contaminate lakes or waterways with the product or used containers. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. OTHER INFORMATION

The veterinary medicinal product is available in four pack sizes - 250 ml, and 1 litre high density polyethylene bottles, and 2.5 litre and 5 litre high density polyethylene back-packs.
Not all pack sizes may be marketed.

Approved: 05 January 2022