

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprivalan 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5 mg/ml

3. PACKAGE SIZE

250 ml

1 l

2.5 l

5 l

4. TARGET SPECIES

Cattle (beef and dairy cattle).

5. INDICATIONS

6. ROUTE 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 by the expiry date.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle or backpack in the outer carton in order to 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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/3005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 ml, 1 l HDPE bottle / 2,5 l, 5 l HDPE backpack.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprivalan 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin 5 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 by the expiry date.

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle or backpack in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Eprivalan 5 mg/ml pour-on solution for cattle

2. Composition

Each ml contains:

Active substance:

Eprinomectin 5.0 mg

Excipients:

Butylhydroxytoluene (E321) 0.1 mg

Clear slightly yellow solution.

3. Target species

Cattle (beef and dairy cattle).

4. Indications for use

Treatment of infestation by the following parasites.

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., and *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 eurytarnus*, *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 veterinary medicinal product is formulated only for topical application to beef and dairy cattle, including lactating dairy cattle. 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.

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:

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

Unnecessary use of antiparasitic or use deviating from the instructions given in the package leaflet 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 herd.

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.

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

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. The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

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

Special precautions for safe use in the target species:

For external use only.

The veterinary medicinal 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 veterinary medicinal product at the end of warble fly activity and before the larvae reach their resting sites.

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

People with known hypersensitivity to eprinomectin or to any of the excipients should avoid contact with the veterinary medicinal product.

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

Avoid skin and eye contact with the veterinary medicinal product during treatment and when handling recently treated animals.

Personal protective equipment consisting of rubber gloves, boots and a waterproof coat should be worn when handling the veterinary medicinal product.

In case of accidental eye exposure occurs, flush eyes immediately with water, seek medical advice and show the package leaflet or the label to the physician.

In case of accidental spillage onto skin, wash the affected area immediately with soap and water seek medical advice and show the package leaflet or the label to the physician.

This veterinary medicinal product may be toxic after accidental ingestion. Avoid accidental ingestion of the veterinary medicinal product by hand to mouth contact.

In case of accidental ingestion, rinse mouth with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Should clothing become contaminated, remove as soon as possible and launder before re-use.

Do not smoke, eat or drink while handling the veterinary medicinal product.

Wash hands after use.

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 repeated use of eprinomectin (and products of the same anthelmintic class).

In order to reduce the risk to aquatic ecosystems, treated animals should not have direct access to water bodies for two to five weeks after treatment.

Pregnancy:

Can be used during pregnancy.

Fertility:

Studies have demonstrated a wide safety margin. Studies conducted at three times the recommended use level of 0.5 mg/kg bodyweight of eprinomectin had no adverse effect on breeding performance of cows or bulls.

Lactation:

Can be used in dairy cattle during all stages of lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

No signs of toxicity appeared when 8-week old calves were treated at up to 5 times the therapeutic dose (2.5 mg/kg bodyweight of eprinomectin) 3 times at 7-day intervals.

One calf treated once at 10 times the therapeutic dose (5 mg/kg bw) in the tolerance study showed transient mydriasis. There were no other adverse reactions to the 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.

7. Adverse events

Cattle (beef and dairy cattle):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Pruritus and alopecia.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Pour-on use.

For single application only.

Administer only by topical application at the dose rate of 0.5 mg/kg bodyweight of eprinomectin, corresponding to the recommended dose rate of 1 ml per 10 kg bodyweight.

9. Advice on correct administration

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible, accuracy of the dosing device should be thoroughly 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.

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

The veterinary medicinal product should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

For 250 ml and 1 litre 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 backpacks:

Connect the dosing gun and draw-off tubing to the backpack 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 periods

Meat and offal: 15 days.

Milk: Zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the bottle or backpack 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 precautions for the disposal

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

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.

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

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 61700/3005

Pack sizes:

250 ml, and 1 litre HDPE bottle

2.5 litres and 5 litre HDPE backpack

250 ml bottle with dose dispenser of 25 ml.

1 litre bottle with dose dispenser of 60 ml.

2.5 litre and 5 litre backpack with a high-density polyethylene polypropylene co-polymer dispensing cap.

One bottle or one backpack per cardboard box.

The 2.5 litre and 5 litre back-packs are designed for use with a suitable automatic dispensing gun.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Boehringer Ingelheim Vetmedica GmbH

Binger Strasse 173

55216 Ingelheim am Rhein

Germany

Contact details to report suspected adverse reactions:

Boehringer Ingelheim Animal Health UK Limited

Ellesfield Avenue

Bracknell

Berkshire

RG12 8YS

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

Local representative and contact details to report suspected adverse reactions:

17. Other information

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.

Gavin Hall
Approved: 02 December 2025