

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Eprinex Multi 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), sheep and goats.

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Pour-on use.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:

**Cattle:**

Meat and offal: 15 days.

Milk: zero hours.

**Sheep:**

Meat and offal: 2 days.

Milk: zero hours.

**Goats:**

Meat and offal: 1 day.

Milk: zero hours.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

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

**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 61700/5011  
Vm 61700/3015

**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**

Eprinex Multi 5mg/ml pour-on solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Eprinomectin 5 mg/ml

250 ml

1 L

2.5 L

5 L

**3. TARGET SPECIES**

Cattle (beef and dairy cattle), Sheep and Goats.

**4. ROUTES OF ADMINISTRATION**

Pour-on use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal periods:

**Cattle:**

Meat and offal: 15 days.

Milk: zero hours.

**Sheep:**

Meat and offal: 2 days.

Milk: zero hours.

**Goats:**

Meat and offal: 1 day.

Milk: zero hours.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

**7. SPECIAL STORAGE PRECAUTIONS**

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

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Vetmedica GmbH

**9. BATCH NUMBER**

Lot {number}

## **B. PACKAGE LEAFLET**

## PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

### 1. Name of the veterinary medicinal product

Eprinex Multi 5 mg/ml Pour-on Solution for Cattle, Sheep and Goats

### 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), sheep and goats.

### 4. Indications for use

Treatment of infestation by the following parasites:

#### Cattle

##### 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. punctata*, *C. surnabada*, *C. pectinata*, *Haemonchus placei*, *Nematodirus helvetianus*, *Trichostrongylus axei*, *Trichostrongylus* spp., *T. colubriformis*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*.

Adult forms of *O. lyrata*, *Trichuris* spp., *Oesophagostomum* spp.

##### Lungworm:

L4 larvae and adult forms of *Dictyocaulus viviparus*.

##### Warbles:

Parasitic stages of *Hypoderma bovis*, *H. lineatum*.

##### Mange mites:

*Chorioptes bovis*, *Sarcoptes scabiei* var. *bovis*.

##### Lice:

*Linognathus vituli*, *Damalinea bovis*, *Haematopinus eurysternus*, *Solenopotes capillatus*.

##### Flies:

*Haematobia irritans*.

Prolonged activity: Control of further infestation for up to:

- 28 days for *Dictyocaulus viviparus*, *Ostertagia ostertagi*., *Oesophagostomum radiatum*, *Cooperia punctata*, *C. surnabada*, *C. oncophora*
- 21 days for *Trichostrongylus axei*, *T. colubriformis*, *Haemonchus placei*
- 14 days for *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.

### **Sheep**

Gastrointestinal roundworms (adult):

*Teladorsagia circumcincta (pinnata/trifurcata)*  
*Haemonchus contortus*  
*Trichostrongylus axei*  
*T. colubriformis*  
*Nematodirus battus*  
*Cooperia curticei*  
*Chabertia ovina*  
*Oesophagostomum venulosum*.

Lungworm (adult):

*Dictyocaulus filaria*

Nasal Bots (L1, L2, L3):

*Oestrus ovis*

### **Goats**

Gastrointestinal roundworms (adult):

*Teladorsagia circumcincta (pinnata/trifurcata)*  
*Haemonchus contortus*  
*Trichostrongylus axei*  
*T. colubriformis*  
*Nematodirus battus*  
*Cooperia curticei*  
*Oesophagostomum venulosum*.

Lungworm (adult):

*Dictyocaulus filaria*

Nasal Bots (L1, L2, L3):

*Oestrus ovis*

Warbles (L1, L2, L3):

*Przhevalskiana silenus*

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

## **5. Contraindications**

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 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.

In cattle, rainfall before, during or after the application of the veterinary medicinal product, has been shown to have no impact on its efficacy. It also has been demonstrated that haircoat length has no impact on the veterinary medicinal product's efficacy.

The effect of rainfall and haircoat length on efficacy has not been evaluated in sheep and goats.

In order to limit cross-transfer of eprinomectin, treated animals should preferably be separated from untreated animals. Non-compliance with this recommendation may lead to residue violations in untreated animals and development of resistance to eprinomectin.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC 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 in cattle while resistance to eprinomectin has been reported in goats and sheep within the EU. However, resistance to other macrocyclic lactones has been reported in nematode populations in cattle, sheep and goat within the EU, which may be associated with side-resistance to eprinomectin. 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 the active substance 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. Avoid contact with eyes and skin.

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

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

In case of accidental skin contact, wash the affected area immediately with soap and water.

In case of accidental eye exposure, flush eyes immediately with plenty of clean water.

Should irritation persist, seek medical advice and show the package leaflet or the label to the physician.

Do not ingest.

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

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 and lactation:

The veterinary medicinal product can be used in dairy cattle during 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. Laboratory studies in cattle have not produced any evidence of a teratogenic or foetotoxic effect at the recommended therapeutic dose.

The safety of eprinomectin during pregnancy in sheep and goats has not been tested. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interactions:

None known.

Since eprinomectin binds extensively to plasmatic 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 were observed when 8-week-old calves were treated at up to 5 times the therapeutic dose (2.5 mg eprinomectin/kg bodyweight.) 3 times at 7-day intervals. One calf treated once at 10 times the therapeutic dose (5 mg/kg bodyweight.) in the tolerance study showed transient mydriasis. There were no other adverse reactions to the treatment.

No signs of toxicity were observed when 17-week-old sheep were treated at doses up to 5 times the therapeutic dose (5 mg eprinomectin/kg bodyweight) 3 times at 14-day intervals.

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), sheep; goats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):  
Pruritus (itching) and alopecia (hair loss).

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>  
e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

Pour-on use.  
For single application only.

Cattle:

Administer 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.

Sheep and goats:

Administer by topical application at the dose rate of 1.0 mg/kg bodyweight of eprinomectin, corresponding to the recommended dose rate of 2 ml per 10 kg bodyweight.

## **9. Advice on correct administration**

For external use only.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

If animals are to be treated collectively, reasonably homogeneous group should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one. Accuracy of the dosing device should be thoroughly checked. Underdosing could result in ineffective use and may favour resistance development.

In sheep and goats, when administering the veterinary medicinal product along the backline, part the fleece/coat and place applicator nozzle or bottle spout against the skin.

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 with dose dispenser:

- 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 designed for use with a suitable automatic dispensing gun:

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**

### **Cattle:**

Meat and offal: 15 days.

Milk: zero hours.

### **Sheep:**

Meat and offal: 2 days.

Milk: zero hours.

### **Goats:**

Meat and offal: 1 day.

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. Store containers upright.

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.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter watercourses as eprinomectin may be dangerous for fish and other aquatic organisms. Do not contaminate lakes or waterways with the veterinary medicinal 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 how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Vm 61700/5011

Vm 61700/3015

Pack sizes:

250 ml and 1 L HDPE bottle.

2.5 L and 5 L HDPE backpacks.

250 ml with 2 dose dispensers (1 of 60 ml for cattle, 1 of 25 ml for sheep/goats).

2.5 L and 5 L backpacks with a high-density polyethylene polypropylene co-polymer dispensing cap.

One bottle or one back-pack per cardboard box.

The 2.5 litre and 5 litre backpacks 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](http://www.gov.uk).

## **16. Contact details**

### Marketing authorisation holder and contact details to report suspected adverse reactions:

Boehringer Ingelheim Vetmedica GmbH  
Binger Strasse 173  
55216 Ingelheim am Rhein  
Germany  
+353 1 291 3985

### Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS  
4 Chemin du Calquet  
31000 Toulouse  
France

## **17. Other information**

POM-V

### Environmental properties:

Extremely dangerous to fish and aquatic life.

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.

*Gavin Hall*  
Approved: 28 November 2025