PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pereprin 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 (dairy cattle and cattle for meat production), sheep, goats

5. INDICATIONS

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}
Once opened use within 1 year.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container 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

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS

UK(NI) Vm 30282/3031
UK(GB) Vm 30282/5028

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {bottle of 250 ml, 1 l, 2.5 l or 5 l)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pereprin 5 mg/ml pour-on solution.

2. STATEMENT OF ACTIVE SUBSTANCES

Eprinomectin	5 mg/ml

3. TARGET SPECIES

Cattle (dairy cattle and cattle for meat production), sheep, 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}

Once opened use within 1 year.

Once opened, use by:

7. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pereprin 5 mg/ml pour-on solution for cattle, sheep and goats.

2. Composition

Each ml contains:

Active substances:

Eprinomectin	5 mg

Excipients:

Butylhydroxytoluene (E 321)	0.1 mg

Colourless or light yellow oily-like liquid.

3. Target species

Cattle (dairy cattle and cattle for meat production), sheep, goats.

4. Indications for use

For treatment of infestations with the following parasites:

Cattle:

PARASITE	ADULT	L4	Inhibited L4
Gastrointestinal Roundworms:			
Ostertagia spp.	◆	◆	
O. lyrata	◆		
O. ostertagi	◆	◆	◆
Cooperia spp.	◆	◆	◆
C. oncophora	◆	◆	
C. pectinata	◆	◆	
C. punctata	◆	◆	
C. surnabada	◆	◆	
Haemonchus placei	◆	◆	
Trichostrongylus spp.	◆	◆	
T. axei	◆	◆	
T. colubriformis	◆	◆	
Bunostomum phlebotomum	◆	◆	
Nematodirus helvetianus	◆	◆	
Oesophagostomum spp.	◆		

Oesophagostomum radiatum	◆	◆
Trichuris spp.	◆	
Lungworm:		
Dictyocaulus viviparus	◆	◆

Warbles (parasitic stages):
Hypoderma bovis
H. lineatum,

Mange mites:
Chorioptes bovis
Sarcoptes scabiei var. bovis,

Lice:
Damalinia bovis (biting lice)
Linognathus vituli (sucking lice)
Haematopinus eurysternus (sucking lice)
Solenopotes capillatus (sucking lice)

Flies:
Haematobia irritans.

PROLONGED ACTIVITY:

Applied as recommended, the veterinary medicinal product prevents reinfestations with:

Parasite	Prolonged Activity
Dictyocaulus viviparus	Up to 28 days
Ostertagia ostertagi	Up to 28 days
Oesophagostomum radiatum	Up to 28 days
Cooperia punctata	Up to 28 days
Cooperia surnabada	Up to 28 days
Cooperia oncophora	Up to 28 days
Nematodirus helvetianus	Up to 14 days
Trichostrongylus colubriformis	Up to 21 days
Trichostrongylus axei	Up to 21 days
Haemonchus placei	Up to 21 days

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

Lungworm (adults):
Dictyocaulus filaria

Nasal Bots (L1, L2, L3):
Oestrus ovis

Goats:

Gastrointestinal roundworms (adults):
Teladorsagia circumcincta (pinnata/trifurcata)
Haemonchus contortus
Trichostrongylus axei
Trichostrongylus colubriformis
Nematodirus battus
Cooperia curticei
Oesophagostomum venulosum

Lungworm (adults):
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 may 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 package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the 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.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (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 goats within the EU, which may be associated with side-resistance to eprinomectin. The use of the 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 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:
This veterinary medicinal product may be irritating to skin and eyes and may cause hypersensitivity reactions.

People with known hypersensitivity to eprinomectin, butylhydroxytoluene or propylene glycol dicaprylocaprate should avoid contact with the veterinary medicinal product.
Eprinomectin can be transferred to breast milk. Therefore, breast-feeding women should handle the veterinary medicinal product with great care.
Avoid contact with eyes and skin.
Personal protective equipment consisting of rubber gloves, boots and waterproof coat 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 spillage on skin, wash the affected area immediately with soap and water.
In case of accidental eye contact, 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 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:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or embryotoxic effects.

Cattle:
Laboratory studies in cattle have not produced any evidence of a teratogenic or foetotoxic effects at the recommended dose. The veterinary medicinal product can be used in dairy cattle during pregnancy and lactation.

Sheep and goats:
The safety of the veterinary medicinal product has not been established during pregnancy in sheep and goats.
Use only according to the benefit-risk assessment of the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
No interactions with other medicines and no other forms of interactions are 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 appeared when 8-week old calves were treated at up to 5x the therapeutic dose (2.5 mg eprinomectin/kg bodyweight) 3 times at 7-day intervals.

One calf treated once at 10x the therapeutic dose (5 mg/kg bodyweight) in the tolerance study with an eprinomectin-containing veterinary medicinal product showed transient mydriasis. There were no other adverse reactions to treatment.

No clinical 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 (dairy cattle and cattle for meat production), sheep and goats:

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

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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: 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 eprinomectin per kg bodyweight, 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 eprinomectin per kg bodyweight, corresponding to the recommended dose rate of 2 ml per 10 kg bodyweight.

9. Advice on correct administration

To ensure a correct dosage, bodyweight should be determined as accurately as possible. If animals are to be treated collectively reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one. Underdosing could result in ineffective use and may favour resistance development.

Accuracy of the dosing device should be checked.

The veterinary medicinal product should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead. When administering the veterinary medicinal product along the backline, part the fleece/coat and place the dosing gun nozzle or measuring pourer cap against the skin.

Method of administration
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 spigot cap that is included in the pack.
- Replace shipping cap with the spigot cap having the draw-off tubing. Tighten the spigot 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.

For the 250 millilitre and 1 litre bottles:
Both bottle types can be used with an appropriate dosing system such as a dosing gun and coupling spigot cap or a measuring pourer cap combined with a dip tube.

For use with a dosing gun: Unscrew the polypropylene cap. Remove the protective seal from the bottle. Screw a coupling spigot cap on the bottle and make sure it is tightened. Attach draw-off tubing to the spigot cap and connect the other end to a dosing gun. Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun and spigot cap. After use, coupling spigot caps should be removed and replaced by the polypropylene cap during storage.

For use with a measuring pourer cap and dip tube: Follow the manufacturer's directions for adjusting the dose and proper use and maintenance of the measuring pourer cap and dip tube.
Unscrew the polypropylene cap. Remove the protective seal from the bottle. Insert the dip tube into the underside of the measuring pourer cap. Screw the measuring pourer cap on the top of the bottle. Squeeze the bottle gently to fill the measuring pourer cap to the required dose as to the manufacturer’s instructions. Release your grip and any excess liquid will return to the bottle. Apply the full dose by tipping and pouring along the back line of the animal until the measuring pourer cap is empty. After use, measuring pourer cap and dip tube should be removed and replaced by the polypropylene cap during storage.

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.

Store in the original container 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 container after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging:1 year.

12. Special precautions for disposal

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

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.

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 or pharmacist 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

UK(NI) Vm 30282/3031
UK(GB) Vm 30282/5028

Pack sizes:
Box containing 250 ml bottle with a spigot cap.
Box containing 1 l bottle with a spigot cap and backpack strap.
Box containing 2.5 l bottle with a spigot cap and backpack strap.
Box containing 5 l bottle with a spigot cap and backpack strap.

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 and contact details to report suspected adverse reactions:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

17. Other information

POM-VPS

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.