1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Multi 5 mg/ml pour-on solution for cattle, sheep and goats (AT, BE, BG, HR, CY, CZ, EE, FR, EL, HU, IE, IT, LV, LT, LU, NL, PL, PT, RO, SK, SI, ES, UK)
Eprinex vet. 5 mg/ml pour-on solution for cattle, sheep and goats (DK, FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Eprinomectin ..... 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E321)	0.1 mg
Propylene glycol dicaprylocaprate	

Clear slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and dairy cattle), sheep, goats.

3.2 Indications for use for each target species

Treatment of infestation by the following parasites:

Cattle:

Parasite	**Adult**	**L4**	**Inhibited L4**
Gastrointestinal Roundworms:			
Ostertagia spp.	◆	◆	
O. lyrata	◆		
O. ostertagi	◆	◆	◆
Cooperia spp.	◆	◆	◆
C. oncophora	◆	◆	
C. punctata	◆	◆	
C. surnabada	◆	◆	
C. pectinata	◆	◆	
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
Hypoderma lineatum

Mange mites:
Chorioptes bovis
Sarcoptes scabiei var. *bovis*

Lice:
Linognathus vituli
Damalinia bovis
Haematopinus eurysternus
Solenopotes capillatus

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 (adult):
Dictyocaulus filaria

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

Goats:

Gastrointestinal roundworms (adult):
Teladorsagia circumcincta (pinnata/trifurcata)
Haemonchus contortus
Trichostrongylus axei
Trichostrongylus colubriformis
Nematodirus battus
Cooperia curticei
Oesophagotomum 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.

3.3 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.

3.4 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 goats 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.

3.5 Special precautions for use

Special precautions for safe use 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 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 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 skin contact occurs, wash the affected area immediately with soap and water.
In case of accidental eye exposure occur, 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.

3.6 Adverse events

Cattle (beef and dairy cattle), sheep, goats:

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

Pour-on use.
For single application 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..
Underdosing could result in ineffective use and may favour resistance development.

Dosage:

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

Method of administration:
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 back-packs designed for use with a suitable automatic dispensing gun:
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA04.

4.2 Pharmacodynamics

Eprinomectin is a member of the macrocyclic lactone class of endectocides. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve or muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite.
Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).
The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels; the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels, and they do not readily cross the blood-brain barrier.

4.3 Pharmacokinetics

Eprinomectin is bound extensively to plasma proteins (99 %).

Pharmacokinetic studies have been conducted in lactating and non-lactating animals, administered topically at a single dosage of 0.5 mg/kg body weight in cattle and at 1 mg/kg bodyweight in sheep and goats.

For cattle, results from two representative studies found mean peak plasma concentrations of 9.7 and 43.8 ng/ml that were observed at 4.8 and 2.0 days post dose. The corresponding elimination half-lives in plasma were 5.2 and 2.0 days, and mean area-under-the-curve values of 124 and 241 ng*day/ml.

Eprinomectin is not extensively metabolized in cattle following topical administration.
Faeces was the major route of elimination of the drug in beef cattle and dairy cows.

For sheep, a mean peak plasma concentration (C_{max}) of 6.20 ng/ml was observed following a topical dose of 1 mg/kg. The half-life in plasma was 6.4 days with mean area under the curve (AUC_{last}) value of 48.8 ng*day/ml.

For goats, peak mean plasma concentrations ranging from 3 to 13.1 ng/ml were observed on average from 17 hours to 2 days post dose. The mean half-life in plasma ranged from one day to up to 5 days with area under the curve mean values ranging from 15.7 to 39.1 ng*day/ml.

An *in vitro* microsomal metabolism study was conducted using liver microsomes isolated from cattle, sheep and goats. It showed that the differences in pharmacokinetics observed between cattle, sheep and goats do not result from differences in the rate or extent of metabolism but suggests more complete absorption of eprinomectin by cattle.

Environmental properties:
Extremely dangerous to fish and aquatic life (see also section 5.5).

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: see expiry date.

5.3 Special precautions for storage

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.
Store container upright.

5.4 Nature and composition of immediate packaging

250 ml and 1 l HDPE bottle
2.5 and 5 l HDPE backpack
Sealed foil and tamper evident HDPE screw cap with polypropylene liner.

250 ml bottle with 2 dose dispensers of 25 ml (1 for cattle, 1 for sheep/goat)
1 l bottle with 2 dose dispensers (1 of 60 ml for cattle, 1 of 25 ml for sheep/goat)
2.5 l backpack with a high-density polyethylene polypropylene co-polymer dispensing cap.
5 l 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

The 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 veterinary medicinal product or used containers.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBERS

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: dd/mm/yyyy

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX III

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. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

Withdrawal period:
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 container in the outer carton in order to protect from light.
Store container 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

14. MARKETING AUTHORISATION NUMBERS

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 5 mg/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 period:

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 container in the outer carton in order to protect from light.
Store container upright.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

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): *Hypoderma bovis, H. lineatum.*

Mange mites: *Chorioptes bovis, Sarcoptes scabiei* var. *bovis.*

Lice: *Linognathus vituli, Damalinia 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 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 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 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 skin contact occurs, wash the affected area immediately with soap and water.
In case of accidental eye exposure occur, 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 interaction:
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 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.

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

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.
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 back-packs 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 container 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.

Shelf life after first opening the immediate packaging: see expiry date.
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 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.

The 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 veterinary medicinal 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 numbers and pack sizes

Pack sizes:
250 ml and 1 l HDPE bottle
2.5 l and 5 l HDPE backpack
250 ml bottle with 2 dose dispensers of 25 ml (1 for cattle, 1 for sheep/goat)
1 l bottle with 2 dose dispensers (1 of 60 ml for cattle, 1 of 25 ml for sheep/goat)
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 backpacks are designed for use with a suitable automatic dispensing gun.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

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

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:
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.