

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EPRINOVET MULTI 5 mg/ml pour-on solution for cattle, sheep and goats

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
All-rac- α -tocopherol (E307)	0.025 mg
Propylene glycol dicaprylocaprate	

Clear faint yellow oily liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and dairy cattle), sheep and 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			
<i>Ostertagia spp.</i>	◆	◆	
<i>Ostertagia lyrata</i>	◆		
<i>Ostertagia ostertagi</i>	◆	◆	◆
<i>Cooperia spp.</i>	◆	◆	◆
<i>Cooperia oncophora</i>	◆	◆	
<i>Cooperia punctata</i>	◆	◆	
<i>Cooperia surnabada</i>	◆	◆	
<i>Cooperia pectinata</i>	◆	◆	
<i>Haemonchus placei</i>	◆	◆	
<i>Trichostrongylus spp.</i>	◆	◆	
<i>Trichostrongylus axei</i>	◆	◆	
<i>Trichostrongylus colubriformis</i>	◆	◆	

<i>Bunostomum phlebotomum</i>	◆	◆	
<i>Nematodirus helvetianus</i>	◆	◆	
<i>Oesophagostomum spp.</i>	◆		
<i>Oesophagostomum radiatum</i>	◆	◆	
<i>Trichostrongylus axei</i>	◆		
Lungworms			
<i>Dictyocaulus viviparus</i>	◆	◆	

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 product prevents reinfestations with

Parasite	Prolonged Activity
<i>Dictyocaulus viviparus</i>	Up to 28 days
<i>Ostertagia ostertagi</i>	Up to 28 days
<i>Oesophagostomum radiatum</i>	Up to 28 days
<i>Cooperia punctata</i>	Up to 28 days
<i>Cooperia surnabada</i>	Up to 28 days
<i>Cooperia oncophora</i>	Up to 28 days
<i>Nematodirus helvetianus</i>	Up to 14 days
<i>Trichostrongylus colubriformis</i>	Up to 21 days
<i>Trichostrongylus axei</i>	Up to 21 days
<i>Haemonchus placei</i>	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 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 product, has been shown to have no impact on its efficacy. It also has been demonstrated that haircoat length has no impact on the 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 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.

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. 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.

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

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 in the target species:

For external use only.

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.

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

People with known hypersensitivity to eprinomectin, butylhydroxytoluene and propylene glycol dicaprylocaprate, should avoid contact with the veterinary medicinal product.

This product may be irritating to skin and eyes. Avoid contact with skin and eyes.

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 dermal exposure, wash skin immediately with soap and water.

In the event of accidental eye contact, wash the eye with plenty of clean water. If irritation persists, seek medical advice and show the package leaflet.

Do not ingest.

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

Wash hands after use.

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

Special precautions for the protection of the environment:

The use of the veterinary medicinal product poses a risk to dung fauna and aquatic and sediment organisms. 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.

Based on the excretion profile of eprinomectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first 7 days after treatment.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding repeated use of eprinomectin (and products of the same anthelmintic class). The product should be used only according to the summary of product characteristics instructions.

3.6 Adverse events

Cattle, sheep and goats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pruritus Alopecia
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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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, or embryotoxic effects for eprinomectin.

Cattle:

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

Sheep and goats:

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

3.8 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.

3.9 Administration routes and dosage

Pour-on use. For single application only.

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

To ensure a correct dosage, body weight 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. All the animals belonging to the same group should be treated at the same time.

Accuracy of the dosing device should be thoroughly checked.

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

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.

When administering the product along the backline, part the fleece/coat and place nozzle of dosing gun against the skin.

Method of administration:

To be used with an appropriate dosing system such a dosing gun and coupling vented cap.

Unscrew the polypropylene (PP) simple cap. Remove the protective seal from the bottle. Screw a coupling vented cap on the bottle and make sure it is tightened. Connect the other side to a dosing gun. Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun and vented cap.

After use, coupling vented caps should be removed and replaced by PP simple cap.

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 with eprinomectin containing veterinary medicinal product 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 plasmatic proteins (99%).

Pharmacokinetic studies with eprinomectin containing veterinary medicinal product 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 with eprinomectin containing veterinary medicinal product found mean peak plasma concentrations (C_{max}) of 9.7 and 43.8 ng/mL that were observed at 4.8 and 2.0 days post dose. The corresponding terminal half-lives in plasma were 5.2 and 2.0 days, and mean area-under-the-curve (AUC) 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.. The terminal 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 (C_{max}) ranging from 3 to 13.1 ng/mL were observed on average from 17 hours to 2 days post dose. The mean terminal half-life in plasma ranged from one day to up to 5 days with area under the curve (AUC) 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

Eprinomectin is toxic to aquatic organisms, is very 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: 5 years.
Shelf life after first opening the immediate packaging: 2 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

White high-density polyethylene (HDPE) bottle sealed with a wax/polyolefin seal and closed with a white polypropylene screw cap.

Pack sizes:

Box with a 2.5 L bottle.

Box with a 5 L bottle.

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

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

The veterinary medicinal product should not enter water courses as eprinomectin may be dangerous for fish and other aquatic organisms.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

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

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month 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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Individual cardboard box for a bottle of 2.5 L or 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EPRINOVET MULTI 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:

Eprinomectin 5.0 mg/ml

3. PACKAGE SIZE

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}

Once opened use within 2 years.

Use by:

9. SPECIAL STORAGE PRECAUTIONS

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

Laboratorios Calier, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 2.5 L or 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EPRINOVET MULTI 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:

Eprinomectin 5.0 mg/ml

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}

Once opened use within 2 years.

Use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

EPRINOVET 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

All-rac- α -tocopherol (E307) 0.025 mg

Clear faint yellow oily liquid.

3. Target species

Cattle (beef and dairy cattle), sheep and goats

4. Indications for use

Treatment of infestation by the following parasites:

Cattle:

Parasite	Adult	L4	Inhibited L4
Gastrointestinal Roundworms			
<i>Ostertagia spp.</i>	◆	◆	
<i>Ostertagia lyrata</i>	◆		
<i>Ostertagia ostertagi</i>	◆	◆	◆
<i>Cooperia spp.</i>	◆	◆	◆
<i>Cooperia oncophora</i>	◆	◆	
<i>Cooperia punctata</i>	◆	◆	
<i>Cooperia surnabada</i>	◆	◆	
<i>Cooperia pectinata</i>	◆	◆	
<i>Haemonchus placei</i>	◆	◆	
<i>Trichostrongylus spp.</i>	◆	◆	
<i>Trichostrongylus axei</i>	◆	◆	
<i>Trichostrongylus colubriformis</i>	◆	◆	
<i>Bunostomum phlebotomum</i>	◆	◆	
<i>Nematodirus helvetianus</i>	◆	◆	
<i>Oesophagostomum spp.</i>	◆		
<i>Oesophagostomum radiatum</i>	◆	◆	

<i>Trichuris spp.</i>	◆		
Lungworms			
<i>Dictyocaulus viviparus</i>	◆	◆	

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 product prevents reinfestations with

Parasite	Prolonged Activity
<i>Dictyocaulus viviparus</i>	Up to 28 days
<i>Ostertagia ostertagi</i>	Up to 28 days
<i>Oesophagostomum radiatum</i>	Up to 28 days
<i>Cooperia punctata</i>	Up to 28 days
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<i>Cooperia oncophora</i>	Up to 28 days
<i>Nematodirus helvetianus</i>	Up to 14 days
<i>Trichostrongylus colubriformis</i>	Up to 21 days
<i>Trichostrongylus axei</i>	Up to 21 days
<i>Haemonchus placei</i>	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 *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 warningsSpecial warnings:

For effective use, the 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 product, has been shown to have no impact on its efficacy. It also has been demonstrated that haircoat length has no impact on the 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 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.

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.

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.

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

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 product should be applied only on healthy skin.

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

People with known hypersensitivity to eprinomectin, butylhydroxytoluene and propylene glycol dicaprylocaprate should avoid contact with the veterinary medicinal product.

This product may be irritating to skin and eyes. Avoid contact with skin and eyes.

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 dermal exposure, wash skin immediately with soap and water.

In the event of accidental eye contact, wash the eye with plenty of clean water. If irritation persists, seek medical advice and show the package leaflet.

Do not ingest.

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

Wash hands after use.

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

Special precautions for the protection of the environment:

The use of the veterinary medicinal product poses a risk to dung fauna and aquatic and sediment organisms. 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.

Based on the excretion profile of eprinomectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first 7 days after treatment.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding repeated use of eprinomectin (and products of the same anthelmintic class). The product should be used only according to the package leaflet instructions..

Pregnancy and lactation:

Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, or embryotoxic effects for eprinomectin.

Cattle:

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

Sheep and goats:

The safety of eprinomectin 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 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 with eprinomectin containing veterinary medicinal product 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.

Special restrictions for use and special conditions for use:

Not applicable.

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, sheep and goats:

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

Method of administration for 2.5 and 5 litre back-packs:

To be used with an appropriate dosing system such a dosing gun and coupling vented cap.

Unscrew the polypropylene (PP) simple cap. Remove the protective seal from the bottle. Screw a coupling vented cap on the bottle and make sure it is tightened. Connect the other side to a dosing gun. Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun and vented cap.

After use, coupling vented caps should be removed and replaced by PP simple cap.

9. Advice on correct administration

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

To ensure a correct dosage, body weight 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. All the animals belonging to the same group should be treated at the same time.

Accuracy of the dosing device should be thoroughly checked.

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

For sheep and goats, when administering the product along the backline, part the fleece/coat and place nozzle of dosing gun against the skin.

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.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 2 years.

12. Special precautions for disposal

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

The veterinary medicinal product should not enter water courses as eprinomectin may be dangerous for fish and other aquatic organisms.

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

Pack sizes:

Box with a 2.5 L bottle

Box with a 5 L bottle

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

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

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

LABORATORIOS CALIER, S.A. [EL, ES, FR, HR, IT, RO, SK]
Calle Barcelonés 26
Polígono Industrial del Ramassà

08520 Les Franqueses del Vallès
Barcelona
Spain

CALIER PORTUGAL, S.A. [PT]
Centro Empresarial Sintra-Estoril II
Rua Pé de Mouro, Edifício
C Estrada de Albarraque
2710 - 335 Sintra
Portugal

Manufacturer responsible for batch release:

LABORATORIOS CALIER S.A.
C. Barcelonès, 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona
Spain

Local representatives and contact details to report suspected adverse reactions:

[To be completed nationally]

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder>.

17. Other information

Eprinomectin is toxic to aquatic organisms, is very persistent in soils and may accumulate in sediments.