Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprecis 20 mg/ml solution for injection for cattle, sheep and goats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Eprinomectin 20.0 mg
Excipients:
Butylhydroxytoluene (E321) 0.8 mg
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and goats.

4.2 Indications for use, specifying the target species

Treatment of infestations by the following internal and external parasites sensitive to eprinomectin:

Cattle

	Adult	L4	Inhibited L4
Gastrointestinal roundworms			
Ostertagia ostertagi	●	●	●
Ostertagia lyrata	●		
Ostertagia spp.	●	●	
Cooperia oncophora	●	●	
Cooperia pectinata	●	●	
Cooperia surnabada	●	●	
Cooperia punctata	●	●	
Cooperia spp.	●	●	●
Haemonchus placei	●	●	
Trichostrongylus axei	●	●	
Trichostrongylus colubriformis	●	●	
Trichostrongylus spp.	●	●	
Bunostomun phlebotomum	●	●	
Nematodirus helvetianus	●	●	
Oesophagostomum radiatum	●	●	
Oesophagostomum spp.	●		
Trichuris spp.	●		
Lungworms			
Dictyocaulus viviparus	●	●	

Sucking lice: *Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus*
Horn flies: *Haematobia irritans*
Warbles (parasitic stages): *Hypoderma bovis, Hypoderma lineatum*

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

Prevention of reinfestations:
The product protects treated animals against reinfestations with:

- *Trichostrongylus* spp. (including *Trichostrongylus axei* and *Trichostrongylus colubriformis*), *Haemonchus placei*, *Cooperia* spp. (including *Cooperia oncophora, Cooperia punctata, Cooperia surnabada*), *Dictyocaulus viviparus, Oesophagostomum radiatum, Ostertagia* spp.(including *Ostertagia ostertagi* and *Ostertagia lyrata*) and *Nematodirus helvetianus* for 14 days.
- *Haematobia irritans* for at least 7 days. **Sheep****Gastrointestinal roundworms (adult)***Teladorsagia circumcincta (pinnata/trifurcata),Haemonchus contortus Trichostrongylus axeiTrichostrongylus colubriformisNematodirus battusCooperia curticeiChabertia ovinaOesophagostomum venulosum* **Lungworm (adult)***Dictyocaulus filaria* **Goats****Gastrointestinal roundworms (adult)***Teladorsagia circumcincta (pinnata/trifurcata) Haemonchus contortus Trichostrongylus axeiTrichostrongylus colubriformisNematodirus battusCooperia curticeiOesophagotomum venulosum* **Lungworm (adult)***Dictyocaulus filaria*

4.3 Contraindications

Do not use in other animal species.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer orally or by intramuscular or by intravenous injection.

4.4 Special warnings for each target species

Cattle, sheep and goats
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device (if any). 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.

If there is a risk for re-infection, the advice of a veterinarian should be sought regarding the need for and frequency of repeat administration.

Cattle
Resistance to other macrocyclic lactones has been reported in parasite species in cattle within the EU. 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.

Sheep and goats
Resistance to eprinomectin in parasite species in goats and sheep has been reported within the EU. 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.

4.5 Special precautions for use

Special precautions for use in animals
Usual aseptic procedures for administration of a parenteral injection should be followed.
Not to be used in other species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.
The death of warble fly larvae in the oesophagus or spinal cord canal may lead to secondary reactions. In order to avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or the spine, it is recommended to administer the product at the end of the period of fly activity and before the larvae reach their resting site.

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

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

The veterinary medicinal product causes serious eye irritation. Avoid contact with the eyes. Wash any splashes from eyes immediately with water.

This product may cause neurotoxicity. Care should be taken when handling the product to avoid self-injection. In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid contact with the skin. Wash any splashes from skin immediately with water.

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

Wash hands after use.

The excipient glycerol formal may cause harm to the unborn child. In addition, the active substance eprinomectin can be transferred to breast milk. Pregnant/breast-feeding women and women of childbearing age should therefore avoid exposure to this product.

Other precautions

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 too frequent and repeated use of eprinomectin (and products of the same anthelmintic class) in cattle, sheep and goats.

The risk to aquatic ecosystems will be further reduced by keeping treated cattle, sheep and goats away from water bodies for two to five weeks after treatment.

4.6 Adverse reactions (frequency and seriousness)

Cattle:

Following treatment, moderate to severe swelling at the site of injection is very common. Typically, the swelling resolves within 7 days, but induration (hardness) may persist for in excess of 21 days. Swelling may be associated with mild to moderate pain. This reaction disappears without any treatment and does not impair the safety or efficacy of the veterinary medicinal product.

Sheep and goats:

Slight to moderate swelling at the injection site is very common. Typically the swelling resolves within 16 to 18 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Cattle:

Can be used during pregnancy and lactation.

Sheep and goats:

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

4.8 Interaction with other medicinal products and other forms of interactions

Since eprinomectin binds strongly to plasma proteins, this should be taken into account if it is used in association with other molecules having the same characteristics.

4.9 Amounts to be administered and administration route

Subcutaneous use. For single administration only.

Administration of 0.2 mg of eprinomectin per kg bodyweight; corresponding to 0.1ml of the veterinary medicinal product per 10 kg bodyweight.

In goats, the volume per injection site should not exceed 0.6 ml.

50 ml and 100 ml vials

Do not exceed 30 broachings per vial. If more than 30 broachings are required, use of a draw off needle is recommended.

250 ml and 500 ml vials
Do not exceed 20 broachings per vial. If more than 20 broachings are required, use of a draw off needle is recommended.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Cattle, sheep:
After subcutaneous administration of up to 5 times the recommended dose, no adverse events were observed except a transient reaction (swelling followed by induration) at the injection site.

The safety of the product in goats has not been demonstrated in overdose studies.

4.11 Withdrawal period(s)

Cattle:
- Meat and offal: 63 days
- Milk: zero hours.

Sheep:
- Meat and offal: 42 days
- Milk: zero hours.

Goats:
- Meat and offal: 42 days
- Milk: zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: endectocides, macrocyclic lactones, avermectins.
ATC vet code: QP54AA04

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Absorption
In cattle, following subcutaneous administration, the bioavailability of eprinomectin is about 89%. The maximal mean plasma concentration of 58 µg/L was reached after 36-48 h.
In lactating sheep, the maximal mean plasma concentration of 19.5 µg/L was reached 33.6 hours after subcutaneous administration. The area under the curve mean value over a period of 7 days after dose injection was 73.3 µg*day/L.
In non-lactating sheep, the maximal mean plasma concentration of 11.3 µg/L was reached after 26.7 hours after dose administration. The area under the curve mean value over a period of 7 days after treatment was 42.5 µg*day/L
In goats, the maximal mean plasma concentration of 20.7 µg/L was reached 36 h after administration. The area under the curve mean value over a period of 7 days was 66.8 µg*day/L.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range from 0.1 to 0.4 mg/kg. Eprinomectin is highly bound (greater than 99%) to plasma proteins.

Metabolism
Eprinomectin is not extensively metabolised. Metabolites amount to approximately 10% of the total residues in plasma, milk, edible tissues and faeces.

Elimination
In cattle, eprinomectin is eliminated with a half-life of 65-75 h and the major route of elimination is via faeces.
In sheep, eprinomectin is eliminated with a comparable half-life of 62-78 h.
In goats, eprinomectin is eliminated with a half-life of 91 hours.

Environmental properties
Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of eprinomectin may take place over a period of several weeks. Faeces containing eprinomectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation. Eprinomectin is very toxic to dung fauna and aquatic organisms, is persistent in soils and may accumulate in sediments.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Dimethyl sulfoxide
Glycerol formal stabilised

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of immediate packaging:
Amber multilayer plastic vials (polypropylene / ethylene vinyl alcohol / polypropylene) with bromobutyl rubber stoppers and aluminium caps and plastic flip-off discs in a cardboard box.

Pack sizes:
50 ml vial
100 ml vial
250 ml vial
500 ml vial

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty container.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 September 2015
Date of last renewal: 25 August 2020

10 DATE OF REVISION OF THE TEXT

July 2021