Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprecis 20 mg/ml solution for injection for cattle

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.

4.2 Indications for use, specifying the target species

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

	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.

4.3 Contraindications

Do not use in other animal species.
Do not use in case of hypersensitivity to active substance or to any of the excipients.

4.4 Special warnings for each target species

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.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported within the EU. However 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.

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.
To avoid adverse reactions due to the death of warble larvae in the oesophagus or backbone, it is recommended to administer the product after the end of warble fly activity and before the larvae reach their resting sites in the body; consult a veterinary surgeon regarding the appropriate time for treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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.
Do not use the product in known cases of sensitivity to the active substance or to any of the excipients.

Other precautions
Eprinomectin is very toxic to 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.
The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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.
Single administration of 0.2 mg of eprinomectin per kg bodyweight; corresponding to 1 ml of the veterinary medicinal product per 100 kg bodyweight.

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

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.

4.11 Withdrawal Period(s)

Meat and offal: 63 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 properties

Absorption
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.

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 cattle plasma proteins.

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

Elimination
Eprinomectin is eliminated with a half-life of 65-75 h and the major route of elimination is via faeces.

5.3 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 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 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 and plastic flip capsule 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

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 Sante Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10815/024/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th September 2015

10 DATE OF REVISION OF THE TEXT