# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box containing 1 vial of 50 ml**
**Cardboard box containing 1 vial of 100 ml**
**Cardboard box containing 1 vial of 250 ml**
**Cardboard box containing 1 vial of 500 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprecis 20 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 20 mg of eprinomectin.

## 3. PACKAGE SIZE

50 ml
100 ml
250 ml
500 ml

## 4. TARGET SPECIES

Cattle, sheep and goats.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Subcutaneous use.

## 7. WITHDRAWAL PERIODS

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: 42days
Milk: zero hours

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 6 months 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

## 14. MARKETING AUTHORISATION NUMBERS

Vm 15052/3009

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**100 ml vial label**
**250 ml vial label**
**500 ml vial label**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprecis 20 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 20 mg of eprinomectin.

## 3. TARGET SPECIES

Cattle, sheep and goats.

## 4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

**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: 42days
Milk: zero hours

## 6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 6 months by: ___/___/___

## 7. SPECIAL STORAGE PRECAUTIONS

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

## 9. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**50 ml vial label**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprecis

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Eprinomectin: 20 mg/ml

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 6 months by: ___/___/___

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:

## 1. Name of the veterinary medicinal product

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

## 2. Composition

Each ml contains:

**Active substance:**
Eprinomectin: 20.0 mg

**Excipients:**
Butylhydroxytoluene (E321): 0.8 mg

Clear colourless to pale yellow solution

## 3. Target species

Cattle, sheep and goats.

## 4. Indications for use

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 veterinary medicinal 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 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*

## 5. Contraindications

Do not use in other 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.
Do not administer orally or by intramuscular or by intravenous injection.

## 6. Special warnings

Special warnings

**Cattle, sheep and goats**

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 based on its epidemiological features, for each herd/flock.
Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd/flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd/flock 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/flock 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.
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 veterinary medicinal 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 veterinary medicinal 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.

Special precautions for safe use in the target species:

Usual aseptic procedures for administration of a parenteral injection should be followed.
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 veterinary medicinal 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 veterinary medicinal product may cause neurotoxicity. Care should be taken when handling the veterinary medicinal 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 veterinary medicinal product.

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 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.

Pregnancy and lactation:
**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.

Interactions 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.

Overdose:
**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 veterinary medicinal product in goats has not been demonstrated in overdose studies.

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:**

| | |
|---|---|
| Very common<br>(> 1 animal / 10 animals treated): | Injection site swelling[1], Injection site pain[2] |

[1] Moderate to severe, typically resolves within 7 days but induration may persist for in excess of 21 days.
[2] Mild to moderate this reaction disappears without any treatment and does not impair the safety or efficacy of the veterinary medicinal product

**Sheep and goats:**

| | |
|---|---|
| Very common<br>(> 1 animal / 10 animals treated): | Injection site swelling[1]<br>Immediate pain upon injection[2] |

[1] Slight to moderate, typically resolves within 16 to 18 days
[2] Manifested by head movements and discomfort in sheep

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 using the contact details at the end of this leaflet, or via your national reporting system.

## 8. Dosage for each species, routes and method of administration

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.

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 homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
Accuracy of the dosing device should be thoroughly checked.

## 9. Advice on correct administration

## 10. Withdrawal periods

**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

## 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 carton or label after “Exp”. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 6 months.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
This veterinary medicinal product should not enter water courses as eprinomectin may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty container.
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

MA: Vm 15052/3009
Pack sizes:
Cardboard box containing 1 vial of 50 ml, 100 ml, 250 ml or 500 ml.

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:

Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, 10. av. de La Ballastière, 33500 Libourne, France.

## 17. Other information

**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.

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