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 for cattle, sheep and goats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 20 mg of eprinomectin.
Butylhydroxytoluene (E321) 0.8 mg

3. PACKAGE SIZE

50 ml
100 ml
250 ml
500 ml

4. TARGET SPECIES

Cattle, sheep and goats.

5. INDICATION(S)

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: 42 days
Milk: zero hours

8. EXPIRY DATE

Exp. {MM/YYY}
Once broached, use within 6 months by: _____/___/____

9. SPECIAL STORAGE PRECAUTIONS

Keep vial in the outer carton

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House Mercury
Park Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5041

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Pregnant women and women of childbearing age should avoid exposure to this product.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V - To be supplied only on veterinary prescription

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 for cattle, sheep and goats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 20 mg of eprinomectin.
Butylhydroxytoluene (E321) 0.8 mg

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: 42 days
Milk: zero hours

6. EXPIRY DATE

Exp. {MM/YYY}
Once broached, use within 6 months by: _____/___/____

7. SPECIAL STORAGE PRECAUTIONS

Keep vial in the outer container

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House Mercury
Park Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

100 ml
250 ml
500 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

15. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/5041

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Eprinomectin: 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {MM/YYY}
Once broached, use within 6 months by: _____/___/____

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

6. ROUTE(S) OF ADMINISTRATION

SC

7. WITHDRAWAL PERIOD

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

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE 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 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: *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: *Oestrus ovis*

5. CONTRAINDICATIONS

Do not use in other animal species.
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 WARNING(S)

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.

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.

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 (symptoms, emergency procedures, antidotes):

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.

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 (>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 (>1 animal / 10 animals treated):	Injection site swelling[1]

[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 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 last section of the package leaflet for respective contact details.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicine 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. Once the vial is broached, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V - To be supplied only on veterinary prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5041
Pack sizes:
50 ml vial
100 ml vial
250 ml vial
500 ml vial

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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.

Approved 06 November 2023