ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 1 bottle of 250 ml
Cardboard box containing 1 bottle of 1 L
Cardboard box containing 1 bottle of 2.5 L
Cardboard box containing 1 bottle of 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 5 mg of eprinomectin.

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

250 ml
1 L
2.5 L
5 L

5. TARGET SPECIES

Cattle (beef and dairy cattle)
Sheep
Goats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

For the 250 ml presentation:
Keep the bottle in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
[Only for those countries where the product is available subject to prescription:]
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. 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

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 15052/4072

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 ml bottle label
1-litre bottle label
2.5-litre bottle label
5-litre bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 5 mg of eprinomectin.

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

250 ml
1 L
2.5 L
5 L

5. TARGET SPECIES

Cattle (beef and dairy cattle)
Sheep
Goats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Once opened, use within 6 months, by: ___/___/___

11. SPECIAL STORAGE CONDITIONS

For the 250 ml presentation:
Keep the bottle in the outer carton in order to protect from light.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
[Only for those countries where the product is available subject to prescription:]
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. 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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4072

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
1-litre bottle label
2.5-litre bottle label
5-litre bottle label
[Label with no outer carton nor package leaflet]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

1 ml contains:
Active substance: 5 mg of eprinomectin.
Excipients: 0.10 mg of butylhydroxytoluene (E321) and 0.06 mg of all-rac-α-tocopherol (E307).
Pale yellow to yellow clear solution.

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1 L
2.5 L
5 L

5. TARGET SPECIES

Cattle (beef and dairy cattle)
Sheep
Goats

6. INDICATION(S)

Treatment of infections by the following endo- and ectoparasites 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.	●	●	
Bunostomum phlebotomum	●	●	
Nematodirus helvetianus	●	●	
Oesophagostomum radiatum	●	●	
Oesophagostomum spp.	●		
Trichuris spp.	●		
Lungworms			
Dictyocaulus viviparus	●	●	

Warbles (parasitic stages): *Hypoderma bovis*, *Hypoderma lineatum;*
Mange mites: *Chorioptes bovis*, *Sarcoptes scabiei* var. *bovis;*
Sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*;
Biting lice: *Damalinia (Bovicola) bovis*;
Flies: *Haematobia irritans.*

Prevention of reinfections:
The veterinary medicinal product protects the animals against reinfections with:
- *Nematodirus helvetianus* for 14 days.
- *Trichostrongylus colubriformis, Trichostrongylus axei* and *Haemonchus placei* for 21 days.
- *Dictyocaulus viviparus, Cooperia oncophora, Cooperia punctata, Cooperia surnabada, Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days.

For best results, this 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

Goats:
Gastrointestinal roundworms (adult)
Teladorsagia circumcincta (pinnata/trifurcata)
Haemonchus contortus
Trichostrongylus axei
Trichostrongylus colubriformis
Nematodirus battus
Cooperia curticei
Oesophagostomum venulosum
Lungworm (adult)
Dictyocaulus filaria

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use. For single application only.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible and accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and overdosing.
All the animals belonging to the same group should be treated at the same time.

Cattle:
Administer only by topical application at the dose rate of 0.5 mg eprinomectin per kg b.w., corresponding to the recommended dose rate of 1 ml of the veterinary medicinal product per 10 kg b.w. The veterinary medicinal product should be applied along the backline in a narrow strip extending from the withers to the tailhead.

Sheep and goats:
Administer only by topical application at the dose rate of 1.0 mg eprinomectin per kg b.w, corresponding to the recommended dose rate of 2 ml of the veterinary medicinal product per 10 kg b.w. When administering the veterinary medicinal product along the backline, part the fleece/coat and place applicator nozzle or bottle spout against the skin.

Method of administration:
To be used with an appropriate dosing system such as 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.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications
This veterinary medical product is formulated only for topical application for cattle, sheep and goats, including lactating animals.
Do not administer orally or by injection.
Do not use in other animal species.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipient(s).

Adverse reactions
In very rare cases, pruritus and alopecia have been observed after the use of the veterinary medicinal product.
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).

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

Special warnings for each target species
For effective use, the veterinary medicinal product should not be applied to areas of the backline covered with mud or manure. The product should be applied only on healthy skin.

In order to limit cross-transfer of eprinomectin, treated animals may be separated from untreated animals. Non-compliance with this recommendation may lead to residue violations in untreated animals.

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.

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 body weight, misadministration of the veterinary medicinal 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 in cattle while resistance to eprinomectin has been reported in sheep and goats 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 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.

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 use in animals
For external use only.
The veterinary medicinal product should be applied only on healthy skin.
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 veterinary medicinal product at the end of the period of fly activity and before the larvae reach their resting site.
The details provided in overdose section apply.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This veterinary medicinal product may be irritating to the skin and eyes. Avoid contact with eyes and skin.
Operators should wear rubber gloves, boots and waterproof coat when applying the veterinary medicinal product. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water. Should irritation persist, seek medical advice
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use. Should clothing become contaminated, remove as soon as possible and launder before re-use.
Do not ingest. In the event of ingestion, wash out mouth with water and seek medical advice and show the package leaflet or the label to the physician.

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

Eprinomectin can be transferred to breast milk. Therefore, breast-feeding users should handle the product with great care.

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 animals away from water bodies for two to five weeks after treatment.

Pregnancy and lactation
Laboratory studies (rat, rabbit) have not produced any evidence of a teratogenic or embryotoxic effects due to the use of eprinomectin at therapeutic doses. Laboratory studies in cattle have not produced any evidence of a teratogenic or foetotoxic effect at the recommended therapeutic dose. Can be used in dairy cattle during pregnancy and lactation.
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.

Overdose (symptoms, emergency procedures, antidotes)
No clinical signs of toxicity appeared when 8-week old calves were treated at up to 5x the therapeutic dose (2.5 mg Eprinomectin/kg b.w.) 3 times at 7-day intervals.
One calf treated once at 10x the therapeutic dose (5 mg/kg b.w.) in the tolerance study showed transient mydriasis.
There were no other adverse reactions to treatment.
No clinical 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.

Incompatibilities
Not applicable.

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.

10. EXPIRY DATE

EXP:
Once opened, use within 6 months, by: ___/___/___

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on this bottle after EXP. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

The veterinary medicinal product is dangerous for aquatic organisms. Do not contaminate lakes and streams with the veterinary medicinal product or with used containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
[Only for those countries where the product is available subject to prescription:]
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
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, Z.I. Très le Bois, 22600 Loudéac, France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4072

17. MANUFACTURER'S BATCH NUMBER

Lot:

Other information

Pack sizes
Box containing 1 bottle of 250 ml
Box containing 1 bottle of 1 L
Box containing 1 bottle of 2.5 L
Box containing 1 bottle of 5 L
1-litre bottle
2.5-litre bottle
5-litre bottle

Not all pack sizes may be marketed.

Environmental properties
See section "Other precautions".
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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Eprecis 5 mg/ml pour-on solution for cattle, sheep and goats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
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, Z.I. Très le Bois, 22600 Loudéac, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Eprinomectin ..... 5 mg

Excipients:
Butylhydroxytoluene (E321) ..... 0.10 mg
all-rac-α-tocopherol (E307) ..... 0.06 mg

Pale yellow to yellow clear solution

4. INDICATIONS

Treatment of infections by the following endo- and ectoparasites 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.	●	●	
Bunostomum phlebotomum	●	●	
Nematodirus helvetianus	●	●	
Oesophagostomum radiatum	●	●	
Oesophagostomum spp.	●		
Trichuris spp.	●		
Lungworms			
Dictyocaulus viviparus	●	●	

Warbles (parasitic stages): *Hypoderma bovis*, *Hypoderma lineatum;*
Mange mites: *Chorioptes bovis*, *Sarcoptes scabiei* var. *bovis;*
Sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*;
Biting lice: *Damalinia (Bovicola) bovis*;
Flies: *Haematobia irritans.*

Prevention of reinfections:
The veterinary medicinal product protects the animals against reinfections with:
- *Nematodirus helvetianus* for 14 days.
- *Trichostrongylus colubriformis, Trichostrongylus axei* and *Haemonchus placei* for 21 days.
- *Dictyocaulus viviparus, Cooperia oncophora, Cooperia punctata, Cooperia surnabada, Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days.

For best results, this 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

Goats:
Gastrointestinal roundworms (adult)
Teladorsagia circumcincta (pinnata/trifurcata)
Haemonchus contortus
Trichostrongylus axei
Trichostrongylus colubriformis
Nematodirus battus
Cooperia curticei
Oesophagostomum venulosum

Lungworm (adult)
Dictyocaulus filaria

5. CONTRAINDICATIONS

This veterinary medical product is formulated only for topical application for cattle, sheep and goats, including lactating animals.
Do not administer orally or by injection.
Do not use in other animal species.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipient(s).

6. ADVERSE REACTIONS

In very rare cases, pruritus and alopecia have been observed after the use of the veterinary medicinal product.
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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (beef and dairy cattle)
Sheep
Goats

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Pour-on use. For single application only.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible and accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and overdosing.
All the animals belonging to the same group should be treated at the same time.

Method of administration:

For the 250 ml presentation:
The bottle is equipped with an integrating dosing system, and has two openings. One opening is connected to the body of the container and the other one to the dispensing chamber (dosing system).
Unscrew the tamper-evident cap and remove the seal of the dispensing chamber (integrated dosing system allowing 5-ml doses and 10-ml doses).
Squeeze the bottle to fill the dispensing chamber with the required volume of veterinary medicinal product.

For the 1 L, 2.5 L and 5 L presentations:
To be used with an appropriate dosing system such as 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

Cattle:
Administer only by topical application at the dose rate of 0.5 mg eprinomectin per kg b.w., corresponding to the recommended dose rate of 1 ml of the veterinary medicinal product per 10 kg b.w. The veterinary medicinal product should be applied along the backline in a narrow strip extending from the withers to the tailhead.

Sheep and goats:
Administer only by topical application at the dose rate of 1.0 mg eprinomectin per kg b.w., corresponding to the recommended dose rate of 2 ml of the veterinary medicinal product per 10 kg b.w. When administering the veterinary medicinal

product along the backline, part the fleece/coat and place applicator nozzle or bottle spout against the skin.

10. WITHDRAWAL PERIOD(S)

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.

For the 250 ml presentation:
Keep the bottle in the outer carton in order to protect from light.

For the 1 L, 2.5 L and 5 L presentations:
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 WARNING(S)

Special warnings for each target species:
For effective use, the veterinary medicinal product should not be applied to areas of the backline covered with mud or manure. The product should be applied only on healthy skin.

In order to limit cross-transfer of eprinomectin, treated animals may be separated from untreated animals. Non-compliance with this recommendation may lead to residue violations in untreated animals.

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.
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 body weight, misadministration of the veterinary medicinal 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 in cattle while resistance to eprinomectin has been reported in sheep and goats 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 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.

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 use in animals:
For external use only.
The veterinary medicinal product should be applied only on healthy skin.
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 veterinary medicinal product at the end of the period of fly activity and before the larvae reach their resting site.
The details provided in overdose section apply.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may be irritating to the skin and eyes. Avoid contact with eyes and skin.
Operators should wear rubber gloves, boots and waterproof coat when applying the veterinary medicinal product. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water. Should irritation persist, seek medical advice.
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use. Should clothing become contaminated, remove as soon as possible and launder before re-use.
Do not ingest. In the event of ingestion, wash out mouth with water and seek medical advice and show the package leaflet or the label to the physician.
People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.
Eprinomectin can be transferred to breast milk. Therefore, breast-feeding users should handle the product with great care.

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 animals away from water bodies for two to five weeks after treatment.

Pregnancy and lactation:
Laboratory studies (rat, rabbit) have not produced any evidence of a teratogenic or embryotoxic effects due to the use of eprinomectin at therapeutic doses. Laboratory studies in cattle have not produced any evidence of a teratogenic or foetotoxic effect at the recommended therapeutic dose. Can be used in dairy cattle during pregnancy and lactation.
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.

Incompatibilities:
Not applicable.

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):
No clinical signs of toxicity appeared when 8-week old calves were treated at up to 5x the therapeutic dose (2.5 mg Eprinomectin/kg b.w.) 3 times at 7-day intervals.
One calf treated once at 10x the therapeutic dose (5 mg/kg b.w.) in the tolerance study showed transient mydriasis.
There were no other adverse reactions to treatment.
No clinical 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

The veterinary medicinal product is dangerous for aquatic organisms. Do not contaminate lakes and streams with the veterinary medicinal product or with used containers.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

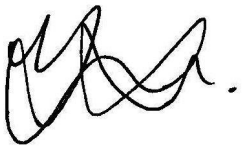
September 2022

15. OTHER INFORMATION

Pack sizes
Box containing 1 bottle of 250 ml
Box containing 1 bottle of 1 L
Box containing 1 bottle of 2.5 L
Box containing 1 bottle of 5 L
1-litre bottle
2.5-litre bottle
5-litre bottle

Not all pack sizes may be marketed.

Environmental properties
See section "Other precautions".
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.



Approved: 28 September 2022