ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Multi 5 mg/ml pour-on solution for cattle, sheep and goats
eprinomectin

2. STATEMENT OF ACTIVE SUBSTANCES

eprinomectin 5 mg/ml

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 and goats.

6. INDICATION(S)

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

Read the package leaflet before use.

User warnings
People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the product. This product may be irritating to skin and eyes. Operators should wear rubber gloves, boots and waterproof coat when applying the product. See package leaflet for full user safety warnings.

10. EXPIRY DATE

EXP {month/year}
Once opened use by the expiry date.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.
Store containers upright.

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

Extremely dangerous to fish and aquatic life. Do not contaminate lakes or waterways with the product or used containers. Disposal: read the package leaflet.

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

For animal treatment only.
[For products subject to veterinary 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

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 08327/3034

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 ml, 1L HDPE bottle, 2.5 L, 5 L HDPE back pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Multi 5mg/ml pour-on solution for cattle, sheep and goats
eprinomectin

2. STATEMENT OF ACTIVE SUBSTANCES

eprinomectin 5 mg/ml

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 and Goats.

6. INDICATION(S)

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

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use by the expiry date.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.
Store container upright.

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.
[For products subject to veterinary 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

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 08327/3034

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Eprinex Multi 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:

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 TOULOUSE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Multi 5 mg/ml pour-on solution for cattle, sheep and goats
eprinomectin

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

Pour-on solution.

Each ml contains:
Active substance:
Eprinomectin 5.0 mg

Excipients:
Butylhydroxytoluene (E321) 0.1 mg

Clear slightly yellow solution.

4. INDICATION(S)

Treatment of infestation by the following parasites sensitive to eprinomectin.

Cattle

Gastrointestinal Roundworms :
Inhibited L4 and L4 larvae, adult forms of *Ostertagia ostertagi*, *Cooperia* spp..
L4 larvae and adult forms of *Ostertagia* spp., *C. oncophora, C. punctata*, *C. surnabada*, *C. pectinata, Haemonchus placei, Nematodirus helvetianus,*

Trichostrongylus axei, Trichostrongylus spp*., T. colubriformis, Bunostomum phlebotomum, Oesophagostomum radiatum.*
Adult forms of *O. lyrata, Trichuris* spp*., Oesophagostomum* spp*.*

Lungworm:
L4 larvae and adult forms of *Dictyocaulus viviparus,*

Warbles:
Parasitic stages of *Hypoderma bovis, H. lineatum*,

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

Lice:
Linognathus vituli, Damalinia bovis, Haematopinus eurysternus, Solenopotes capillatus.

Flies:
Haematobia irritans.

Prolonged activity: Control of further infestation for up to:
- 28 days for *Dictyocaulus viviparus, Ostertagia ostertagi., Oesophagostomum radiatum, Cooperia punctata, C. surnabada, C. oncophora*
- 21 days for *Trichostrongylus axei, T colubriformis, Haemonchus placei*
- 14 days for *Nematodirus helvetianus*

For best results, the 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 (adult)
Teladorsagia circumcincta (pinnata/trifurcata)
Haemonchus contortus
Trichostrongylus axei
T. 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

T. colubriformis
Nematodirus battus
Cooperia curticei
Oesophagostomum venulosum

Lungworm (adult)
Dictyocaulus filaria

Nasal Bots (L1, L2, L3)
Oestrus ovis

Warbles (L1, L2, L3)
Przhevalskiana silenus

For best results the veterinary medicinal product should be part of a programme to control both internal and external parasites of sheep and goats based on the epidemiology of these parasites.

5. CONTRAINDICATIONS

Do not use in other animal 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.

6. ADVERSE REACTIONS

Pruritus and alopecia have been observed in very rare cases, 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.
Alternatively, you can report via your national reporting system {national system details}

7. TARGET SPECIES

Cattle (beef and dairy cattle), sheep and goats.

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

Pour-on use. For single application only.

Cattle:
Administer by topical application at the dose rate of 0.5 mg eprinomectin per kg bodyweight, corresponding to the recommended dose rate of 1 ml per 10 kg bodyweight.

Sheep and goats:
Administer by topical application at the dose rate of 1.0 mg eprinomectin per kg bodyweight, corresponding to the recommended dose rate of 2 ml per 10 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

For external use only.
The product should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; 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 over- dosing. All the animals belonging to the same group should be treated at the same time. Underdosing could result in ineffective use and may favour resistance development.

In sheep and goats, when administering the product along the backline, part the fleece/coat and place applicator nozzle or bottle spout against the skin.

Two dosing systems are available:
250 ml and 1 litre bottles with dose dispenser
• Attach the dose dispenser to the bottle.
• Set the dose by turning the top section of the dose dispenser to align the correct bodyweight with the pointer inside the dose dispenser. When bodyweight is between markings, use the higher setting.
• Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines. By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. For the 1 litre bottle: when a 10 ml or 15 ml dose is required, turn the pointer to “STOP” before delivering the dose. The off (STOP) position will close the system between dosing.
• The dose dispenser should not be stored attached to the bottle when not in use. Remove the dose dispenser after each use and replace with the bottle cap.

2.5 and 5 litre Back packs designed for use with a suitable automatic dispensing gun.
Connect the dosing gun and draw-off tubing to the back-pack as follows:
• Attach the open end of the draw-off tubing to an appropriate dosing gun.
• Attach draw-off tubing to the cap with the stem that is included in the pack.
• Replace shipping cap with the cap having the draw-off tubing. Tighten the draw-off cap.
• Gently prime the dosing gun, checking for leaks.
• Follow the dosing gun manufacturer’s directions for adjusting the dose and proper use and maintenance of the dosing gun and draw-off tubing.

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.
This veterinary medicinal product does not require any special temperature storage conditions.
Keep the container in the outer carton in order to protect from light.
Store containers upright.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: see expiry date.

12. SPECIAL WARNING(S)

Special warnings for each target species:

For effective use, the product should not be applied to areas of the backline covered with mud or manure.

In cattle, rainfall before, during or after the application of the product, has been shown to have no impact on its efficacy. It also has been demonstrated that haircoat length has no impact on the product's efficacy.
The effect of rainfall and haircoat length on efficacy has not been evaluated in sheep and goats.

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

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 infestation based on its epidemiological features, for each herd.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd,

maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd 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 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.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported in cattle while resistance to eprinomectin has been reported in goats and sheep within the EU. However, resistance to other macrocyclic lactones has been reported in nematode populations in cattle, sheep and goat within the EU, which may be associated with side-resistance to eprinomectin.

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
The product should be applied only on healthy skin.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites.

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

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 repeated use of eprinomectin (and products of the same anthelmintic class).
In order to reduce the risk to aquatic ecosystems, treated animals should not have direct access to water bodies for two to five weeks after treatment.
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.

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. The product 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.

Interaction with other medicinal products and other forms of interactions:
No interactions with other medicines and no other forms of interactions are known.
Since eprinomectin binds extensively to plasmatic 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), if necessary
No signs of toxicity were observed when 8-week old calves were treated at up to 5 times the therapeutic dose (2.5 mg eprinomectin/kg bodyweight.) 3 times at 7-day intervals.
One calf treated once at 10 times the therapeutic dose (5 mg/kg bodyweight.) in the tolerance study showed transient mydriasis. There were no other adverse reactions to the treatment.

No 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:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Extremely dangerous to fish and aquatic life. Do not contaminate lakes or waterways with the product or used containers. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

The product is available in four pack sizes: 250 ml, and 1 litre high density polyethylene bottles and 2.5 litre and 5 litre high density polyethylene backpacks.
One bottle or one back-pack per cardboard box.

Not all pack sizes may be marketed.

Gavin Hall
Approved: 06 July 2024