ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 5 ml and 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 0.75 mg/ml solution for injection for dogs

Pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 0.75 mg of pimobendan.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 ml
10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single intravenous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

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. 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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4311

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial, 5 ml and 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 0.75 mg/ml solution for injection for dogs

Pimobendan

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pimobendan 0.75 mg/ml

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

5 ml
10 ml

4. ROUTE(S) OF ADMINISTRATION

IV

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Vetmedin 0.75 mg/ml solution for injection for dogs

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

Manufacturer responsible for batch release:
Labiana Life Sciences S.A.
Calle Venus 26
Pol Ind Can Parellada Industrial
08228 Terrassa
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 0.75 mg/ml solution for injection for dogs

Pimobendan

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

Each ml contains

Active substance:
Pimobendan 0.75 mg

A clear colourless solution.

4. INDICATION(S)

To initiate treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypertrophic cardiomyopathies or clinical conditions where an augmentation of cardiac output is not possible for functional or anatomical reasons (e.g. aortic stenosis).

6. ADVERSE REACTIONS

A moderate positive chronotropic effect and vomiting may occur in rare cases.
In rare cases transient diarrhoea, anorexia or lethargy have been observed.

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

Dogs

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

Single intravenous injection at a dosage of 0.15 mg pimobendan/kg body weight (i.e. 2 ml/ 10 kg body weight).
Vetmedin chewable tablets or Vetmedin capsules for dogs may be used for continuation of treatment at the recommended dosage, to be started 12 hours after administration of the injection.

9. ADVICE ON CORRECT ADMINISTRATION

A 5 ml and a 10 ml vial can treat up to a 25 kg and 50 kg body weight dog respectively.

Each vial is for single use only.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
This product does not contain an antimicrobial preservative.
This product is intended for single use only.
Any product remaining in the bottle after withdrawal of the required dose should be discarded.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
In case of accidental subcutaneous injection temporary swelling and mild to slight resorptive inflammatory reactions can occur at or below the injection site.
For single administration only.

The product should be used for the initiation of treatment of congestive heart failure in dogs, following a risk:benefit assessment by the responsible veterinarian, taking into account the overall health status of the dog. Before treatment, diagnosis should be made by the means of a comprehensive physical and cardiac examination which should include echocardiography or radiography where appropriate.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation:
In studies with rats and rabbits pimobendan had no effect on fertility. Embryotoxic effects only occurred at maternotoxic doses. In rat experiments it has been shown that pimobendan is excreted into milk. Therefore, the product should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risk.

Interaction with other medicinal products and other forms of interaction:
In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the ß-antagonist propranolol.

Overdose (symptoms, emergency procedures, antidotes):
In the case of overdose symptomatic treatment should be initiated.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2023

<15. OTHER INFORMATION>

5 ml or 10 ml single-use injection vial.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 09 February 2023