ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.5 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: pimobendan: 1.5 mg

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 8 weeks.

9. SPECIAL STORAGE PRECAUTIONS

Store below 30°C.

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/3063

15. BATCH NUMBER

Lot {number}

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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.5 mg/ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pimobendan: 1.5 mg/ml

50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Use by …..

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vetmedin 1.5 mg/ml oral solution for dogs

2. Composition

Each ml contains:

Active substance:
Pimobendan: 1.5 mg

Excipients:
Sorbic acid (E200): 3.0 mg
Asorbic acid (E300): 7.0 mg

Clear, colourless to yellow to slightly green to slightly brown solution.

3. Target species

Dogs

4. Indications for use

For the treatment of canine congestive heart failure originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid valve regurgitation).

For the treatment of dilated cardiomyopathy in the preclinical stage (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter) in Doberman Pinschers following echocardiographic diagnosis of cardiac disease.

5. Contraindications

Do not use pimobendan in hypertrophic cardiomyopathies or in diseases in which an improvement in cardiac output cannot be achieved for functional or anatomical reasons (e.g., aortic stenosis).
Do not use in cases of severe impairment of liver function, since pimobendan is metabolised mainly via the liver.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

The veterinary medicinal product has not been tested in cases of asymptomatic DCM in Dobermans with atrial fibrillation or sustained ventricular tachycardia.

Special precautions for safe use in the target species:
In dogs with existing diabetes mellitus, blood glucose should be tested regularly during treatment with pimobendan.
For use in the preclinical stage of dilated cardiomyopathy (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter), a diagnosis should be made by means of a comprehensive cardiac examination (incl. echocardiographic examination and possibly Holter monitoring).

Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to pimobendan or any other excipients should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin and eyes.
In case of contact with the eyes or spillage onto the skin, immediately rinse thoroughly with water. Wash hands after use.

Accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.
To avoid accidental ingestion, do not leave a filled syringe unattended and store the bottle and used syringe in the original carton in order to prevent children from getting access to the veterinary medicinal product.
Close the bottle tightly with the cap directly after removal of the required amount of solution.
The veterinary medicinal product must be used and kept out of sight and reach of children.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or foetotoxic effects. However, these studies have shown evidence of maternotoxic and embryotoxic effects at high doses, and have also shown that pimobendan is excreted into milk.

Interaction with other medicinal products and other forms of interaction:
In pharmacological studies no interaction between the cardiac glycoside ouabain (strophanthin) and pimobendan was observed. The pimobendan-induced increase in cardiac contractility is attenuated by the calcium antagonists verapamil and diltiazem and by the β-antagonist propranolol.

Overdose:
An overdose may cause a positive chronotropic effect, vomiting, apathy, ataxia, heart murmurs or hypotension. In this situation, the dosage should be reduced, and appropriate symptomatic treatment should be initiated.
In prolonged exposure (6 months) of healthy beagle dogs at 3 and 5 times the recommended dose, mitral valve thickening and left ventricular hypertrophy were observed in some dogs. These changes are of pharmacodynamic origin.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):
- Vomiting[1], diarrhoea[2]
- Anorexia[2], lethargy[2]
- Increased heart rate[1,3]
- Increase in mitral valve regurgitation[4]

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
- Mucosa petechiae[5], haemorrhage (subcutaneous)[5]

1 These effects are dose-dependent and can be avoided by reducing the dose.
2 Transient
3 Due to a slight positively chronotropic effect.
4 Observed during chronic pimobendan treatment in dogs with mitral valve disease.
5 A relationship with pimobendan has not been clearly established, signs disappear when the treatment is withdrawn.

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, its local representative using the contact details at the end of this leaflet, or via your national reporting system {national reporting system details}.

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

Oral use.

Do not shake the bottle before or during use to avoid foaming.

To ensure a correct dosage, the bodyweight should be determined as accurately as possible.
A dosage range of 0.2 mg to 0.6 mg pimobendan/kg bodyweight, divided into two daily doses, should be respected. The preferrable daily dose is 0.5 mg pimobendan/kg bodyweight divided into two daily doses given approximately

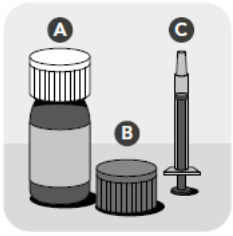
12 hours apart (i.e., 0.25 mg pimobendan/kg bodyweight equivalent to 0.17 ml of the veterinary medicinal product twice daily).

The solution should be given using the measuring syringe provided in the package. The syringe has a kg bodyweight scale with 0.5 kg increments up to a bodyweight of 12 kg and fits onto the bottle. Each 1 kg increment corresponds to 0.25 mg pimonbendan. The total bodyweight of the animal should be used for each administration. For example, for a 6 kg dog, the veterinary medicinal product should be drawn up to the 6 kg mark on the syringe for each administration (this equates to a 0.25 mg pimobendan/kg bodyweight dose per administration). Do not exceed the recommended dosage.

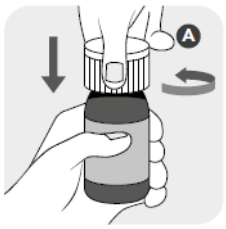
Each dose should be given directly into the mouth on an empty stomach, approximately one hour before feeding. After administration, close the bottle tightly using the cap. Clean the outside of the syringe by wiping with a clean, dry cloth or tissue after each use. The contaminated tissue should be immediately disposed of. If the syringe clogs, rinse without removing the plunger by using water and wiping the outside of the syringe dry with a clean cloth or tissue. To avoid contamination, use the provided syringe only to administer this oral solution. The used syringe should be stored with the veterinary medicinal product in the original carton.

Pimobendan may also be used in combination with a diuretic e.g., furosemide.

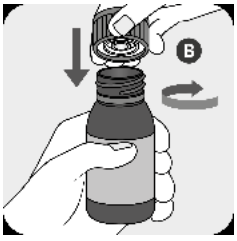
9. Advice on correct administration



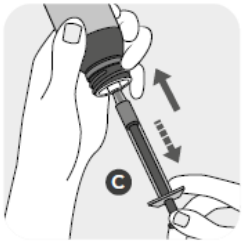
The veterinary medicinal product consists of a bottle sealed with a child-resistant cap **A**, a second child-resistant cap with integrated plug-in adapter **B** and a measuring dosing syringe with a kg-bodyweight scale **C**.



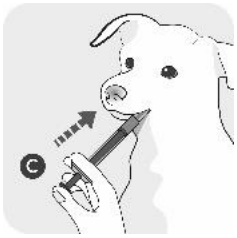
Do not shake the bottle prior to use (this avoids foaming).
Open the bottle in an upright position by pressing down on the child-resistant cap **A** and simultaneously turning the cap **anticlockwise**.
Discard the white cap **A**.



Tightly close the bottle using the cap **B** and turn simultaneously the cap **clockwise**. The cap **B** contains an integrated plug-in adapter which should automatically attach to the bottle **A**. Ensure the cap is tightly closed to appropriately insert plug.



Remove the cap **B** from the bottle by pressing down on the child-resistant cap and simultaneously turning the cap **anticlockwise** and gently push the end of the dosing syringe **C** onto the bottle plug.
Turn the bottle and syringe upside down.
Pull the plunger out and fill the dosing syringe to the dose prescribed by your veterinarian.



Turn the bottle upright and remove the dosing syringe from the bottle Close the bottle with cap **B**.
Put the end of the doing syringe **C** into your dog´s mouth and push the plunger to give the prescribed dose.

The information is available also following this link: info.vetmedin.com

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store below 30°C.
Shelf life after first opening the immediate packaging: 8 weeks.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.

12. Special precautions disposal

Medicines should not be disposed of via wastewater or household waste.
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

Vm 61700/3063

Cardboard box with 1 bottle filled with 50 ml and 1 measuring syringe with a kg bodyweight scale with 0.5 kg increments.

15. 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.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Local representatives and contact details to report suspected adverse events:

Gavin Hall

Approved: 22 April 2025