

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 5 ml and 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 0.75 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 0.75 mg of pimobendan.

3. PACKAGE SIZE

5 ml
10 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Single i.v. use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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 61700/3061

15. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pimobendan 0.75 mg/ml

5 ml

10 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vetmedin 0.75 mg/ml Solution for Injection for Dogs

2. Composition

Each ml contains:

Active substance:

Pimobendan 0.75 mg

Solution for injection.

A clear colourless solution.

3. Target species

Dogs.

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:

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 veterinary medicinal 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:

Embryotoxic effects only occurred at maternotoxic doses. In rat experiments it has been shown that pimobendan is excreted into milk. Therefore, the veterinary medicinal product should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risk.

Fertility:

In studies with rats and rabbits pimobendan had no effect on fertility.

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 β -antagonist propranolol.

Overdose:

In the case of overdose symptomatic treatment should be initiated.

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, diarrhoea ¹
- Anorexia ¹ , lethargy ¹
- Increased heart rate ²

¹ Transient

² Due to a moderate chronotropic effect.

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 or the local representative of the marketing authorisation holder 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

For single intravenous (i.v.) use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The recommended dosage is 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 periods

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 veterinary medicinal product does not contain an antimicrobial preservative.

This veterinary medicinal product is intended for single use only.

Any veterinary medicinal product remaining in the bottle after withdrawal of the required dose should be discarded.

Shelf life after first opening the immediate packaging: use immediately.

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 precautions for 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 61700/3061

5 ml or 10 ml single-use injection vial packed in a cardboard box.
Not all pack sizes may be marketed.

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:

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer responsible for batch release:

LABIANA Life Sciences. S.A. Calle
Venus, 26
Can Parellada Industrial
08228 - Terrassa
Barcelona
Spain

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

Gavin Hall
Approved: 22 August 2025