

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON, 50 ML)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vetmedin 1.5 mg/ml oral solution for dogs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

One ml contains: pimobendan 1.5 mg

**3. PACKAGE SIZE**

50 ml

**4. TARGET SPECIES**

Dogs

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

Store below 30°C.

Once broached, use by:

**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 Animal Health UK Ltd

**14. MARKETING AUTHORISATION NUMBER**

Vm 08327/5028

**15. BATCH NUMBER**

Lot {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

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

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V

Veterinary medicinal product subject to prescription.

**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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE  
SUBSTANCES**

Pimobendan: 1.5 mg/ml

50 ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**5. ROUTE(S) OF ADMINISTRATION**

Oral use

**6. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vetmedin 1.5 mg/ml oral solution for dogs

### **2. COMPOSITION**

One ml contains:

**Active substance:**

Pimobendan 1.5 mg

**Excipients:**

Sorbic acid: 3.0 mg

### **3. TARGET SPECIES**

Dogs

### **4. INDICATIONS FOR USE**

For the treatment of canine congestive heart failure originating from dilated cardiomyopathy 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 (see section "Special warnings" and "Precautions for use in animals").

For the treatment of dogs with myxomatous mitral valve disease (MMVD) in the preclinical stage (asymptomatic with a systolic mitral murmur and evidence of increased heart size) to delay the onset of clinical symptoms of heart failure (see section "Special warnings" and "Precautions for use in animals").

### **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).

Since pimobendan is metabolised mainly via the liver, it should not be used in dogs with severe impairment of liver function.

Do not use in cases of hypersensitivity to pimobendan or to any of the excipients.

## 6. SPECIAL WARNINGS

### Special warnings for the target species:

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

The product has not been tested in cases of asymptomatic myxomatous mitral valve disease in dogs with significant supraventricular and/or ventricular tachyarrhythmia.

### 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).

For use in the preclinical stage of myxomatous mitral valve disease (stage B2, according to ACVIM consensus: asymptomatic with mitral murmur  $\geq$  3/6 and cardiomegaly due to myxomatous mitral valve disease), a diagnosis should be made by means of a comprehensive physical and cardiac examination which should include echocardiography or radiography where appropriate.

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:

Accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches. Do not leave a filled syringe unattended.

This product may cause eye or skin irritation. Avoid skin and eye contact.

In case of accidental eye or skin contact, immediately rinse thoroughly with water.

In case irritation develops or if accidental ingestion occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to pimobendan should avoid contact with the product.

Do not eat, drink, or smoke while handling the product.

Wash hands after use.

### Pregnancy and lactation:

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. The safety of the product has not been assessed in pregnant or nursing bitches. The product should therefore only be administered to pregnant or lactating bitches in accordance with a benefit/risk assessment conducted by the responsible veterinarian.

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  $\beta$ -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.

## 7. ADVERSE EVENTS

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	- Vomiting <sup>1</sup> , diarrhoea <sup>2</sup> - Anorexia <sup>2</sup> , lethargy <sup>2</sup> - Increased heart rate <sup>1,3</sup> - Increase in mitral valve regurgitation <sup>4</sup>
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	- Mucosal petechiae (small red spots on mucosa) <sup>5</sup> , haemorrhages (subcutaneous) <sup>5</sup>

1. A dose-dependent effect can be avoided by reducing the dose.
2. Transient effects.
3. A mild, dose-dependent, positive chronotropic effect can occur that can be avoided by reducing dose.
4. Observed during chronic pimobendan treatment in dogs with mitral valve disease.
5. These signs disappear when the treatment is withdrawn; however, a relationship with pimobendan has not been clearly established.

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 Boehringer Ingelheim Animal Health UK Ltd using the contact details at the end of this leaflet, or via your national reporting system (pharmacovigilance at the Veterinary Medicines Directorate: <https://www.gov.uk/report-veterinary-medicine-problem>).

## **8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION**

For oral use.

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

Determine the bodyweight accurately before treatment to ensure correct dosage.

The recommended dose is 0.25 mg pimobendan/kg bodyweight twice daily (equivalent to 0.17 ml of the veterinary medicinal product twice daily).

Doses should be given approximately 12 hours apart.

Each dose should be given directly into the animal's mouth on an empty stomach, and at least one hour before feeding.

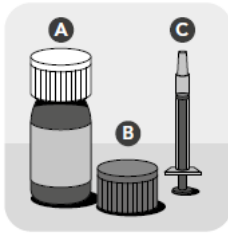
The total bodyweight of the animal should be used to determine the dose for each administration. For example, for a 6 kg dog the veterinary medicinal product should be drawn up into the provided syringe to the 6 kg mark at each twice daily administration. This 6 kg dose equates to the recommended dose of 0.25 mg pimobendan/kg bodyweight twice daily.

A maximal recommended dosage range of 0.1 mg to 0.3 mg pimobendan/kg bodyweight twice daily should be respected (i.e. a total of 0.2 mg to 0.6 mg pimobendan/kg bodyweight per day). Do not exceed the recommended dosage range.

The solution should be given using the measuring syringe provided in the package. A second child-resistant cap with integrated plug-in adapter is provided and should be used after the bottle is first opened. The provided syringe fits onto the bottle and has a kg-bodyweight scale marked. Following administration of the product, any residual product remaining on the tip or outside of the dosing syringe should be wiped clean with a tissue. 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 Vetmedin 1.5 mg/ml oral solution. The used syringe should be stored with the product in the original carton. After administration of the veterinary medicinal product close the bottle tightly with the cap.

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

## 9. ADVICE ON CORRECT ADMINISTRATION

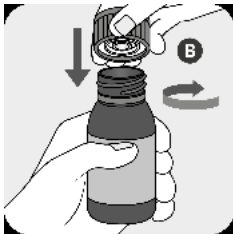


Vetmedin oral solution consists of a bottle sealed with a child-resistant cap **A**, a second child-resistant cap with integrated plug-in adapter **B** and a measuring dosing syringe with a kg-bodyweight scale **C**.

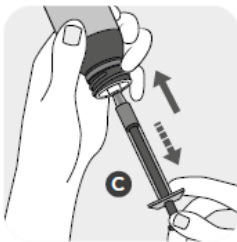


**Do not shake the bottle** prior to use (this avoids foaming).

Open 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.

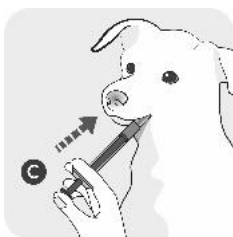


Remove the cap **B** from the bottle by pressing down on the child-resistant cap and simultaneously turning the cap **anticlockwise** and gently push the end of the dosing syringe **C** onto the bottle plug.

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 dosing syringe **C** into your dog's mouth and push the plunger to give the prescribed dose.

## 10. WITHDRAWAL PERIODS

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp.

Shelf life after first opening the immediate packaging: 8 weeks.

Once the bottle is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label.

## **12. SPECIAL PRECAUTIONS FOR DISPOSAL**

Medicines should not be disposed of via wastewater.

Dispose of waste materials in accordance with local requirements

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help protect the environment.

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

POM-V

Veterinary medicinal product subject to prescription

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

A 60 ml glass bottle filled with 50 ml oral solution, sealed with a child-resistant cap. A second child-resistant cap with integrated plug-in adapter and a measuring syringe is also provided and should be used after the bottle is first opened.

Vm 08327/5028

## **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](http://www.gov.uk).

## **16. CONTACT DETAILS**

Marketing authorisation holder:  
Boehringer Ingelheim Animal Health UK Limited  
Ellesfield Avenue  
Bracknell  
RG12 8YS  
United Kingdom

Manufacturer responsible for batch release:

Argenta Dundee Limited  
Kinnoull Road  
Dunsinane Industrial Estate  
Dundee, DD2 3XR

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)  
Boehringer Ingelheim Animal Health UK Ltd  
+44 1344 746957

**17. OTHER INFORMATION**

For animal treatment only.

*Gavin Hall*

Approved: 10 March 2025