# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.5 mg/ml oral solution for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**
Pimobendan: 1.5 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Sorbic acid (E200) | 3.0 mg |
| Hydroxypropylbetadex | |
| Hypromellose | |
| Ascorbic acid (E300) | 7.0 mg |
| Hydrochloric acid dilute (for pH adjustment) | |
| Sodium hydroxide (for pH adjustment) | |
| Water, purified | |

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

## 3. CLINICAL PARTICULARS

### 3.1 Target species

Dogs

### 3.2 Indications for use for each target species

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.

## 3.3 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.

## 3.4 Special warnings

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

## 3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

## 3.6 Adverse events

Dogs:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10 000 animals treated): | - Vomiting[1], diarrhoea[2]<br>- Anorexia[2], lethargy[2]<br>- Increased heart rate[1,3]<br>- Increase in mitral valve regurgitation[4] |
| Very rare<br>(< 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

## 3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in bitches.

Pregnancy and lactation:
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.

## 3.8 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.

## 3.9 Administration routes and dosage

Oral use.

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

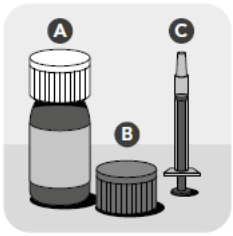
To ensure a correct dosage, the bodyweight should be determined as accurately as possible.
A dosage range of 0.2 mg to 0.6 mg pimobendan/kg bodyweight, divided into two daily doses, should be respected. The preferrable daily dose is 0.5 mg pimobendan/kg bodyweight divided into two daily doses given approximately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

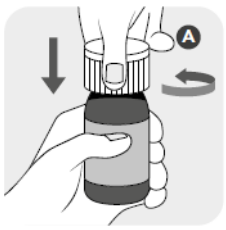
Each dose should be given directly into the mouth on an empty stomach, approximately one hour before feeding. After administration, close the bottle tightly using the cap. Clean the outside of the syringe by wiping with a clean, dry cloth or tissue after each use. The contaminated tissue should be immediately 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.

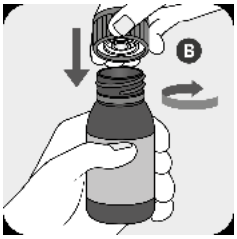
<u>Advice on correct administration</u>



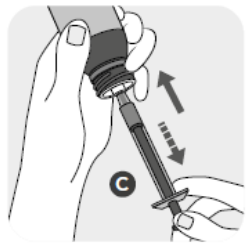

The veterinary medicinal product consists of a bottle sealed with a child-resistant cap **A**, a second child-resistant cap with integrated plug-in adapter **B** and a measuring dosing syringe with a kg-bodyweight scale **C**.



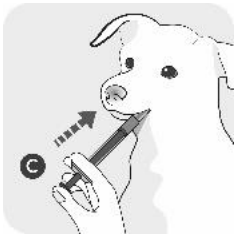

**Do not shake the bottle** prior to use (this avoids foaming). Open the bottle in an upright position by pressing down on the child-resistant cap **A** and simultaneously turning the cap **anticlockwise**. Discard the white cap **A**.




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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes

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.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

**4.1 ATCvet code:** QC01CE90

## 4.2 Pharmacodynamics

Pimobendan, a benzimadazolepyridazinone derivative has a positively inotropic action and possesses pronounced vasodilator properties.

The positive inotropic effect of pimobendan is mediated by two action mechanisms: increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase III. Thus, the positive inotropism is triggered neither by an action similar to that of the cardiac glycosides nor sympathomimetically.
The vasodilator effect arises from inhibition of phosphodiesterase III.

When used in cases of symptomatic valvular insufficiency in conjunction with furosemide the product has been shown to improve the quality of life and extend life expectancy in treated dogs.

When used in a limited number of cases of symptomatic dilated cardiomyopathy in conjunction with furosemide, enalapril and digoxin, the product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

In a randomized and placebo-controlled study including Doberman Pinschers with preclinical dilated cardiomyopathy (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter following echocardiographic diagnosis), the time to onset of congestive heart failure or sudden death was extended and survival time was prolonged among dogs administered pimobendan.
Additionally, there was a reduction in the heart size of dogs treated with pimobendan in the preclinical stage of dilated cardiomyopathy. Efficacy evaluation is based on data from 19 (of 39) and 25 (of 37) dogs that reached the primary efficacy endpoint in the pimobendan and the placebo group, respectively.

## 4.3 Pharmacokinetics

Absorption:
After oral administration of this veterinary medicinal product the absolute bioavailability of its active substance is 60 to 63%. Since simultaneous or previous food intake reduces the bioavailability, pimobendan should be administered approximately 1 hour before feeding.

Distribution:
The volume of distribution is 2.6 l/kg, indicating that pimobendan is distributed readily into the tissues. The mean plasma protein binding is 93%.

Metabolism:
The compound is demethylated by oxidation to the major active metabolite (UD-CG 212). Further metabolic steps are phase II conjugates of UD-CG 212, such as glucuronides and sulphates.

Elimination:
The plasma elimination half-life of pimobendan is 0.8 ± 0.4 hours, which corresponds to the high clearance of 90 ± 19 ml/min/kg and the short mean residence of 1.6 ± 0.6 hours.

The most significant active metabolite is eliminated with a plasma elimination half-life of 1.8 ± 0.6 hours. Almost the entire dose is eliminated in the faeces.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 8 weeks.

### 5.3 Special precautions for storage

Store below 30°C.

### 5.4 Nature and composition of immediate packaging

Amber glass (type III) bottle with a PP child-resistant cap. Additional PP child-resistant cap with integrated LDPE plug-in adapter and a 2 ml syringe with PP barrel and HDPE plunger.
Cardboard box with 1 bottle filled with 50 ml and 1 measuring syringe with a kg bodyweight scale with 0.5 kg increments.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

## 7. MARKETING AUTHORISATION NUMBER

Vm 61700/3063

## 8. DATE OF FIRST AUTHORISATION

03 March 2025

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

March 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

*Gavin Hall*

Approved: 22 April 2025