## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 0.75 mg/ml solution for injection for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**
Pimobendan 0.75 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| *Hydroxypropylbetadex* |
| *Disodium hydrogen phosphate dodecahydrate* |
| *Sodium dihydrogen phosphate dihydrate* |
| *Sodium hydroxide (for pH adjustment)* |
| *Hydrochloric acid (for pH adjustment)* |
| *Water for Injections* |

Solution for injection.
Clear colourless solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs.

### 3.2 Indications for use, for each target species

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

### 3.3 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).

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

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.

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, diarrhoea[1]<br>- Anorexia[1], lethargy[1]<br>- 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 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

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.

### 3.8 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.

### 3.9 Administration routes and dosage

For single intravenous 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).
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.
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.

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

In the case of overdose symptomatic treatment should be initiated.

### 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 benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilatative properties.

Pimobendan exerts its stimulatory myocardial effect by a dual mechanism of action: increase in calcium sensitivity of cardiac myofilaments and inhibition of phosphodiesterase (type III). It also exhibits a vasodilating action through an inhibitory action on phosphodiesterase III activity.

### 4.3 Pharmacokinetics

Absorption:
Due to the intravenous administration, the bioavailability is 100 %.

Distribution:
After intravenous administration 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 oxidatively demethylated to its major active metabolite (UD-CG 212). Further metabolic pathways are phase II conjugates of UD-CG 212, in essence glucuronides and sulfates.

Elimination:
Following intravenous administration, the plasma elimination half-life of pimobendan is 0.4 $\pm$ 0.1 hours, consistent with the high clearance of 90 $\pm$ 19 ml/min/kg and a short mean residence time of 0.5 $\pm$ 0.1 hours.
The main active metabolite is eliminated with plasma elimination half-life of 2.0 ± 0.3 hours. Almost the entire dose is eliminated via 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: 3 years
Shelf life after first opening the immediate packaging: use immediately.

### 5.3 Special precautions for storage

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.

### 5.4 Nature and composition of immediate packaging

Single-use 5 ml or 10 ml colourless injection Type 1 glass vial with a FluroTec coated butyl rubber stopper and sealed with an aluminium cap, packed singly in a cardboard box.
Not all pack sizes may be marketed.

### 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(S)

VPA10454/022/001

## 8. DATE OF FIRST AUTHORISATION

22/08/2014

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

22/03/2024

## 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).