SUMMARY OF PRODUCT CHARACTERISTICS

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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 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).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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 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.

4.6 Adverse reactions (frequency and seriousness)

A moderate positive chronotropic effect and vomiting may occur in rare cases.
In rare cases transient diarrhoea, anorexia or lethargy have been observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

In studies with rats and rabbits pimobendan had no effect on fertility. Embryotoxic effects only occurred at maternotoxic doses. In rat experiments it has been shown that pimobendan is excreted into milk. Therefore, the product should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risk.

4.8 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.

4.9 Amounts to be administered and administration route

Single intravenous injection at a dosage of 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Cardiac stimulants excl. cardiac glycosides, phosphodiesterase inhibitors.
ATC vet code: QC01CE90.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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 adminsitration, 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylbetadex
Disodium hydrogen phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for Injections

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
This product does not contain an antimicrobial preservative.
This product is intended for single use only.
Any product remaining in the bottle after withdrawal of the required dose should be discarded.

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

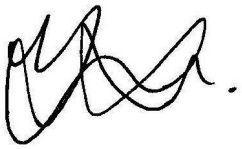
Vm 08327/4311

9. DATE OF FIRST AUTHORISATION

07 August 2014

10. DATE OF REVISION OF THE TEXT

September 2019



Approved: 16 September 2019