

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Active Substance

Pimobendan	1.25 mg
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Excipients

Titanium Dioxide (E171)	0.976 mg
Ferric Oxide Yellow (E172)	0.0439 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsule, hard and yellow/white in colour

4 CLINICAL PARTICULARS

4.1 Target Species

Dog.

4.2 Indications for use, specifying the target species

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

When used in cases of valvular insufficiency in conjunction with frusemide, 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 dilated cardiomyopathy in large breed dogs in conjunction with concomitant standard therapy, the product has been shown to improve the quality of life and to extend life expectancy in treated dogs.

4.3 Contraindications

Vetmedin capsules should not be used 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

This product should be used only in dogs with cardiac insufficiency.
Do not exceed the recommend dosage.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

A moderate positive chronotropic effect and vomiting may occur in rare cases. However, these effects are dose-dependent and may be avoided by reducing the dose in these cases. In rare cases transient diarrhoea, anorexia or lethargy have been observed.

4.7 Use during pregnancy, lactation or lay

In studies with rats and rabbits pimobendan had no effect on fertility and embryotoxic effects only occurred at maternotoxic doses. In experiments with rats it has been shown that pimobendan is excreted into milk. No information is available on the safety of Vetmedin in pregnant and lactating bitches. Therefore, Vetmedin capsules should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risks.

4.8 Interaction with other medicinal products and other forms of interaction

The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the β -antagonist propranolol.

In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected.

4.9 Amounts to be administered and administration route

See dosing guide below.

Vetmedin capsules should be administered orally (approximately one hour before feeding) at a dose of 0.2 mg to 0.6 mg pimobendan/kg bodyweight per day. The daily dose should be divided into two equal administrations, one half of the dose in the morning and the other half approximately 12 hours later.

Determine the bodyweight accurately before prescribing to ensure administration of the correct dosage.

In cases of mild congestive heart failure, a daily dosage at the lower end of the dose range may be adequate. If, however, a clear response is not observable within one week, the dosage should be raised.

Dosing Guide

Note: For larger dogs Vetmedin 2.5mg or 5.0mg capsules are more suitable.

Daily Pimobendan Dosage: 0.2 – 0.6 mg/kg							
No. of capsules per administration							
Body Weight (kg)	Daily Dosage (mg)	Morning			Evening		
		1.25mg	2.5mg	5mg	1.25mg	2.5mg	5mg
<10	2.5	1			1		
10-20	5		1			1	
21-40	10			1			1
41-60	20			2			2
>60	30			3			3

Vetmedin capsules may be combined with a diuretic treatment such as furosemide.

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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Cardiac stimulants, Pimobendan.
ATCvet Code: QC01CE90.

Summary presentation of the active ingredients:
Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilatative properties

5.1 Pharmacodynamic properties

Pimobendan exerts its stimulatory myocardial effect by a dual mode of action: it increases calcium sensitivity of cardiac myofilaments and inhibits phosphodiesterase (type III). It also exhibits a vasodilatory action through inhibition of phosphodiesterase III activity

5.2 Pharmacokinetic properties

Absorption
Following oral administration of Vetmedin capsules the absolute bioavailability of the active principle is 60 – 63%. Since this bioavailability is considerably reduced when pimobendan is administered with food or shortly thereafter, it is recommended to treat animals approximately 1 hour before feeding.

Distribution
The volume of distribution is 2.61/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-CG12). Further metabolic pathways are phase II conjugates of UD-CG 212, in essence glucuronides and sulphates.

Elimination

The plasma elimination half-life of pimobendan is 0.4 ± 0.1 hours which is consistent with a high clearance of 90 ± 19 ml/min/kg and a short mean residence time of 0.5 ± 0.1 hours.

The main active metabolite is eliminated with a 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

Citric acid, anhydrous
Colloidal silica
Microcrystalline cellulose
Povidone
Magnesium stearate
Titanium dioxide (E171)
Ferric oxide yellow (E172)
Gelatin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Keep the container tightly closed.

6.5 Nature and composition of immediate packaging

Vetmedin 1.25 mg capsules are packed in either white polypropylene bottles with white polypropylene child-resistant screw caps, high density polyethylene inner caps and polypropylene spacer or in white high density polyethylene bottles with white polypropylene child-resistant screw-caps. Each bottle contains 100 capsules and is packed in a cardboard carton.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Ltd.,
Ellesfield Avenue,
Bracknell,
Berkshire,
RG12 8YS,
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/029/003

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th November 2008

10 DATE OF REVISION OF THE TEXT

20th May 2009