Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetmedin 5.0 mg Flavour Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

Active Substance:
Pimobendan 5.0 mg

Excipients:
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets.
Meat flavoured, oval scored mottled brown tablets with fine white spots.
The tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

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 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 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

The veterinary medicinal product 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).
See also section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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 has 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. Therefore the veterinary medicinal product should only be administered to pregnant and lactating bitches if the expected therapeutic benefits outweigh the potential risk (See 4.3).

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

This product should be used only in dogs with cardiac insufficiency.
Do not exceed the recommended dose.
Determine the bodyweight accurately before treatment to ensure correct dosage.

The veterinary medicinal product should be administered orally at a dose rate of 0.2 mg to 0.6 mg pimobendan/kg bodyweight per day. The preferable daily dose is 0.5 mg pimobendan/kg bodyweight. The dose should be divided into two administrations (0.25 mg/kg bodyweight each), one half of the dose in the morning and the other half approximately 12 hours later. Each dose should be given approximately one hour before feeding.

Table to show dosing guide					
Daily Pimobendan Dosage: 0.2 – 0.6 mg/kg. The preferable daily dose is 0.5 mg/kg					
		No. of tablets per administration			
Body weight (kg)	**Daily dosage** (mg)	Morning		Evening	
		1.25 mg	5 mg	1.25 mg	5 mg
< 10	2.5	1	-	1	
10 - 20	5	-	½	-	½
21 - 40	10	-	1	-	1
41 - 60	20	-	2	-	2
> 60	30	-	3	-	3

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

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

In the case of overdosage symptomatic treatment should be initiated.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Cardiac stimulant (phosphodiesterase inhibitor)
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: 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 the veterinary product 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 2.6 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 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
Maize starch
Lactose monohydrate
Povidone
Croscarmellose sodium
Irradiated artificial powdered beef flavour
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable.

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^{o}C. Keep the container tightly closed in order to protect from moisture.

6.5 Nature and composition of immediate packaging

A 150 ml high density polyethylene screw-necked bottle with a polypropylene child-resistant closure containing 50 tablets.

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

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

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/043/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th April 2011

10 DATE OF REVISION OF THE TEXT