Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 100 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Propentofylline	100 mg

Excipients:

Titanium dioxide (E171)	0.856 mg
Yellow ferric oxide (E172)	0.258 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Orange yellow oblong tablets, half-scored on both sides, with 'K100' embossed on one side of the tablets.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For the improvement of peripheral and cerebral vascular blood circulation in dogs.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

In the case of specific diseases (e.g. kidney disease), appropriate treatment should be administered.
Consideration should be given to rationalising the medication of dogs already receiving treatment for congestive heart disease or bronchial disease.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, symptoms of cardiac and cerebral over-stimulation (e.g. tachycardia and/or collapse) have been observed. In such cases, animals should be treated symptomatically.
Allergic reactions (e.g. urticaria) may occur in rare cases and these necessitate discontinuation of the treatment.
Vomiting has been observed on rare occasions, particularly at the commencement of therapy.

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

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Oral use.
Dose: 6 – 10 mg propentofylline/kg body weight, divided into two daily doses as follows:

Body weight (kg)	Tablets (am)	Tablets (pm)	Daily total tablets	Daily total dose (mg/kg)
20 – 33 kg	1	1	2	6.0 – 10.0
34 – 49 kg	1½	1½	3	6.1 – 8.8
50 – 66 kg	2	2	4	6.1 – 8.0
67 – 83 kg	2½	2½	5	6.0 – 7.5

The tablet(s) can be administered directly onto the back of the dog’s tongue or can be mixed in a small amount of food.

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

No effects other than those described in section 4.6.
In cases of overdose, animals should be treated symptomatically.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Peripheral vasodilators; purine derivatives.
ATCvet code: QC04AD90

5.1 Pharmacodynamic properties

Propentofylline belongs to the group of xanthine derivatives. In investigations in various animal species it could be demonstrated that propentofylline increases the blood flow to the brain, the heart and skeletal muscle. It inhibits platelet aggregation and improves the flow properties of erythrocytes.

5.2 Pharmacokinetic properties

After oral application propentofylline is quickly and completely absorbed and quickly distributed in the tissues. Given orally to dogs maximum plasma levels are reached within 15 minutes.

The half-life is about 30 minutes and the bioavailability of the parent substance amounts to about 30 %. There are a number of effective metabolites and the biotransformation takes place mainly in the liver. 80 – 90 % of an administered dose is excreted as propentofylline metabolites via the kidneys.The rest is eliminated with the faeces. There is no accumulation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Maize starch
Crospovidone
Talc
Colloidal anhydrous silica
Magnesium stearate

Film coat:
Methylhydroxypropylcellulose
Macrogol 8000
Talc
Titanium dioxide (E171)
Yellow ferric oxide (E172)

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 °C. Store in a dry place.

6.5 Nature and composition of immediate packaging

Blister package: PVC 250µm/Aluminium foil 20µm.
Pack size: Cardboard box with 6 blister strips of 10 tablets (60 tablets).

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

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

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/127/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st September 2001
Date of last renewal: 21st September 2006

10 DATE OF REVISION OF THE TEXT

May 2016