1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 100 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Propentofylline 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Tablet core:
Lactose monohydrate
Maize starch
Crospovidone
Talc
Silica colloidal anhydrous
Magnesium stearate
Film coat:
Hypromellose
Macrogol 8000
Talc
Titanium dioxide (E171)
Iron oxide yellow (E172)

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Rare (1 to 10 animals / 10,000 animals treated):	Tachycardia[1]; Collapse[2]; Allergic reaction (e.g. Urticaria)[3]; Vomiting[4]

[1] Symptom of cardiac over-stimulation. In such cases, animals should be treated symptomatically.
[2] Symptom of cerebral over-stimulation. In such cases, animals should be treated symptomatically.
[3] Necessitate discontinuation of treatment.
[4] Particularly at the commencement of therapy.

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 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:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use only.
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.

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

No effects other than those described in section 3.6.
In cases of overdose, animals should be treated symptomatically.

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:
QC04AD90

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C. Store in a dry place.

5.4 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).
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/127/002

8. DATE OF FIRST AUTHORISATION

21 September 2001

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

03 July 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).