

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Propentofylline 50 mg

Excipients:

| Qualitative composition of excipients and other constituents | Quantitative composition if that information is essential for proper administration of the veterinary medicinal product |
|--|---|
| Maize starch | |
| Crospovidone | |
| Talc | |
| Lactose monohydrate | |
| Magnesium stearate | |
| Silica, colloidal anhydrous | |
| <u>Film Coating</u> | |
| Hypromellose | |
| Talc | |
| Titanium dioxide (E171) | 0.359 mg |
| Iron oxide yellow (E172) | 0.125 mg |
| Macrogol 8000 | |

Ochre, biconvex, round film-coated tablets, quarter scored on one side and embossed on the other side: “K50”.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For improvement in dullness, lethargy and overall demeanour in dogs. The veterinary medicinal product is particularly useful in older dogs, where it may increase willingness to exercise and exercise tolerance.

3.3 Contraindications

Do not administer to pregnant bitches or breeding animals.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Specific diseases (e.g. kidney disease) should be treated accordingly.

In the case of renal failure, the dose should be reduced.

Consideration should be given to rationalising the medication of dogs already receiving treatment for congestive heart failure or bronchial disease.

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

Care should be taken to avoid accidental ingestion.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

| | |
|---|---|
| Rare (1 to 10 animals / 10,000 animals treated): | Vomiting ¹ ; Allergic reaction (e.g., Urticaria) ² |
|---|---|

¹ Particularly at the commencement of therapy.

² Necessitates discontinuation of treatment.

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 its local representative 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:

Do not use in pregnant bitches. The safety of the veterinary medicinal product has not been established during pregnancy.

Fertility:

Do not use in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Half a tablet per 5 kg body weight twice a day (equivalent to 6-10 mg propentofylline per kg bodyweight per day).

Dogs of less than 5 kg may receive a quarter of a tablet twice a day. Dogs of more than 20 kg can be given Vivitonin 100 mg tablets.

The tablets can be administered directly onto the back of the dog's tongue or can be mixed in a small ball of food and should be administered at least 30 minutes before feeding.

Divide the tablets in halves and quarters with a knife or with a tablet splitter.

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

Symptoms of cardiac and cerebral overstimulation have been observed. In such cases, 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 has been shown to increase blood flow, particularly of the heart and skeletal muscle. It also increases the blood flow of the brain and therefore its oxygen supply, without increasing the brain's glucose demand. It has a modest positive chronotropic effect and a marked positive inotropic effect. In addition, it has been shown to have an antiarrhythmic effect in dogs with myocardial ischemia and a bronchodilator action equivalent to that of aminofylline.

Propentofylline inhibits platelet aggregation and improves the flow properties of erythrocytes.

It has a direct effect on the heart and reduces peripheral vascular resistance thereby lowering cardiac load.

4.3 Pharmacokinetics

After oral administration, propentofylline is rapidly and completely absorbed and quickly distributed into the tissues. Maximum plasma levels are reached by 15 minutes following oral dosing in dogs.

The half-life is approximately 30 minutes and the bioavailability of the parent compound is approximately 30%.

There are a number of effective metabolites and biotransformation takes place mainly in the liver.

80-90% of propentofylline is excreted in the form of metabolites via the kidneys. The rest is eliminated with the faeces.

There is no bioaccumulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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.

Keep the blister packs in the outer carton.

5.4 Nature and composition of immediate packaging

Polyvinyl chloride/aluminium foil blister packs of 2 x 30 tablets.

Pack size:

Cardboard box containing 60 tablets, presented in 2 blister strips of 30 tablets.

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

Medicines should not be disposed of via wastewater.

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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4074

8. DATE OF FIRST AUTHORISATION

17 September 1991

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

April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 20 June 2025