SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 50mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	
Propentofylline	50.00mg/tablet
Film coating ingredients:	
Yellow ferric oxide (E172) (colouring)	0.125mg/tablet
Titanium Dioxide (E171) (colouring)	0.359mg/tablet

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Orange-yellow film coated tablets.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

Not to be administered to pregnant bitches or breeding animals.

Do not use in animals with known hypersensitivity to the active substance or any of the excipients.

4.4 Special warning for each target species

None

4.5 Special precautions for use

(i) Special precautions for use in animals

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.

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

Care should be taken to avoid accidental ingestion.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Vomiting has been observed on rare occasions, particularly at the commencement of therapy.
In rare cases allergic reactions (e.g. urticaria) may occur and these necessitate discontinuation of the treatment.

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

Do not use in pregnant bitches as the product has not been evaluated in these animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

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

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

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

Symptoms of cardiac and cerebral overstimulation have been observed. In such cases, animals should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 anti-arrhythmic 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.
ATC Vet Code: QC04AD90

5.2 Pharmacokinetic particulars

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize Starch

Crospovidone
Talc
Magnesium Stearate
Colloidal Anhydrous silica

Film Coating :
Methylhydroxpropylcellulose 5mPa's
Talc
Titanium dioxide (E171)
Yellow ferric oxide (E172)
Macrogol 8000

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^{o}C. Store in a dry place.
Keep blister packs in outer carton.

6.5 Nature and composition of immediate packaging

2 Polyvinylchloride/aluminium blister packs of 30 tablets per carton.

6.6 Special precautions for disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4074

9. DATE OF FIRST AUTHORISATION

17 September 1991

10. DATE OF REVISION OF TEXT

June 2024

Approved 28 June 2024
Gavin Hall