

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vivitonin 100mg tablets

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active substance:

Propentofylline 100.00mg/tablet

Film coating ingredients:

Yellow ferric oxide (E172) (colouring) 0.258mg/tablet

Titanium Dioxide (E171) (colouring) 0.856mg/tablet

For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Ochre, biconvex, oblong filmcoated 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 10kg body weight twice a day

The tablets should not be quartered. More accurate dosing may be achieved using a combination of 100mg and 50mg tablets. Dogs of less than 20kg can be given 50 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 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**

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:**

Methylhydroxypropylcellulose 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°C. Store in a dry place. Return any half tablets to the original packaging. Keep blister packs in outer carton.

### **6.5 Nature and composition of immediate packaging**

Polyvinylchloride/aluminium blister packs of 6 x 10 tablets.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

**7. MARKETING AUTHORISATION HOLDER**

Intervet International BV  
Wim de Korverstraat 35  
5831 AN  
Boxmeer  
Netherlands

**8. MARKETING AUTHORISATION NUMBER**

Vm 06376/4078

**9. DATE OF FIRST AUTHORISATION**

30 September 1994

**10. DATE OF REVISION OF TEXT**

June 2024

Approved 28 June 2024  
*Gavin Hall*