### PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Cardboard box

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

Vivitonin 50 mg tablets

### 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: Propentofylline 50 mg

### 3. PACKAGE SIZE

60 film-coated tablets

#### 4. TARGET SPECIES

Dogs.

### 5. INDICATIONS

#### 6. ROUTES OF ADMINISTRATION

Oral use. Must be given at least 30 minutes before food.

#### 7. WITHDRAWAL PERIODS

#### 8. EXPIRY DATE

Exp. {mm/yyyy}

#### 9. SPECIAL STORAGE PRECAUTIONS

Keep the blister packs in the outer carton. Do not store above 25 °C. Store in a dry place.

# 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

# 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

### 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

### 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

### **14. MARKETING AUTHORISATION NUMBERS**

Vm 06376/4074

#### **15. BATCH NUMBER**

Lot {number}

### MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS Blister packs

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

Vivitonin 50 mg tablets

### 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Propentofylline 50 mg

#### 3. BATCH NUMBER

Lot {number}

### 4. EXPIRY DATE

Exp. {mm/yyyy}

## PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

### PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Vivitonin 50 mg tablets for dogs

# 2. Composition

Each tablet contains:

#### Active substance:

Propentofylline 50 mg

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

### 3. Target species

Dogs.

#### 4. Indications for use

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.

The active ingredient, 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. Propentofylline 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 aminophylline.

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.

### 5. 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.

# 6. Special warnings

None.

<u>Special precautions for safe use in the target species:</u> 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.

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.

Interaction with other medicinal products and other forms of interaction: None known.

<u>Overdose:</u>

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

<u>Major incompatibilities:</u> None known.

# 7. Adverse events

Dogs:

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

<sup>1</sup> Particularly at the commencement of therapy.

<sup>2</sup> Necessitates discontinuation of treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at: Website: <u>https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine</u>

e-mail: adverse.events@vmd.gov.uk

### 8. Dosage for each species, routes and method of administration

Oral use.

Half a tablet per 5 kg body weight twice a 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.

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

### 9. Advice on correct administration

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.

#### 10. Withdrawal periods

Not applicable.

### 11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C. Store in a dry place. Keep the blister packs in the outer carton.

#### **12.** Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13.** Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

### 14. Marketing authorisation numbers and pack sizes

Vm 06376/4074

Pack size:

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

### 15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

### 16. Contact details

Marketing authorisation holder: Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Netherlands

Manufacturer responsible for batch release: Intervet GesmbH Siemensstrasse 107 1210 Vienna Austria

<u>Local representative:</u> MSD Animal Health UK Limited Walton Manor, Walton Milton Keynes, MK7 7AJ, United Kingdom

Contact details to report suspected adverse reactions: **UK(GB)** MSD Animal Health UK Ltd. Tel.: +44 (0)1908 685685 **UK(NI)** Intervet Ireland Ltd. Tel.: +353 (0)1 2970220

<u>Distributor in Northern Ireland:</u> Intervet Ireland Ltd. Magna Drive, Magna Business Park Citywest Road, Dublin 24, Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

# 17. Other information

POM-V Veterinary medicinal product subject to prescription.

Gavin Hall

Approved: 20 June 2025