

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE  
CARTON**

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

Vitofyllin 100 mg film-coated tablets for dogs

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains 100 mg of Propentofylline.

**3. PACKAGE SIZE**

56 tablets or 140 tablets

**4. TARGET SPECIES**

Dogs.

**5. INDICATIONS**

*For products not subject to veterinary prescription*

For the improvement of peripheral and cerebral vascular blood circulation. For improvement in dullness, lethargy and overall demeanour in dogs.

**6. ROUTES OF ADMINISTRATION**

For oral administration.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life of divided tablet portions: 72 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Divided tablets should be stored in the blister packs.  
Keep the blister packs in the outer carton. Store in a dry place.  
Store in the original blister package.

**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**

WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG

**14. MARKETING AUTHORISATION NUMBERS**

Vm 32829/3001

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**BLISTERS**

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

Vitofyllin 100 mg film-coated tablets for dogs

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Propentofylline 100.00 mg/tablet

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Vitofyllin 100 mg film-coated tablets for dogs

### 2. Composition

Active substance:

Each tablet contains 100 mg of propentofylline.

Excipients:

Ferric Oxide, yellow, (E172)	0.150 mg/tablet
Titanium Dioxide, (E171)	0.430 mg/tablet

Film-coated tablets.

Yellow, round, convex tablets with cross breakline tab on one side and imprinting "100" on the other side.

The tablet can be divided into 2 or 4 equal parts.

### 3. Target species

Dogs.

### 4. Indications for use

For the improvement of peripheral and cerebral vascular blood circulation. For improvement in dullness, lethargy and overall demeanour in dogs.

### 5. Contraindications

Refer to section 6. Special warnings, subsection Pregnancy and lactation.

Do not use in pregnant or lactating bitches or breeding animals.

Do not use in dogs weighing less than 5 kg.

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

### 6. Special warnings

Special precautions for safe use in the target species:

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

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

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

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

Care should be taken to avoid accidental ingestion.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation:

The safety of the product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches or breeding animals.

Overdose:

Excitation, tachycardia, hypotension, reddening of mucous membranes and vomiting. The withdrawal of the treatment leads to a spontaneous remission of these signs.

**7. Adverse events**

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):

Allergic skin reactions\*, vomiting\*, cardiac disorder\*

\* In these cases, the treatment should be stopped.

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.

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

The basic dosage is 6-10 mg propentofylline/kg bodyweight daily, divided into two 3-5 mg/kg doses as follows:

<u>Body weight (kg)</u>	<u>Tablets</u>		<u>Daily total</u> <u>tablets</u>	<u>Daily total</u> <u>dose (mg/kg)</u>
	<u>am</u>	<u>pm</u>		
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

To ensure administration of the correct dose, the body weight of the animal should be determined before treatment.

More accurate dosing may be achieved by using either quarters of the 100 mg tablets or a combination of 100 mg and 50 mg tablets. Dogs of less than 20 kg can be given Vitofyllin 50 mg film-coated tablets for dogs.

**9. Advise 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.

Store in the original blister package.

Keep the blister packs in the outer carton.

Store in a dry place.

Unused divided tablets should be returned to the blister pack.

Shelf life of divided tablet portions: 72 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp.

The expiry date refers to the last day of that month.

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

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 applicable national collection systems.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

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

DE: Veterinary medicinal product not subject to prescription.

AT, BE, FR, IE, LU, ES, PT, NL, HU, IT, NI: Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## **14. Marketing authorisation numbers and pack sizes**

Vm 32829/3001

Polyvinylchloride– PolyVinylidene dichloride /Aluminium blister with 14 tablets, in a cardboard box containing 4 blisters (56 tablets).

Polyvinylchloride/– PolyVinylidene dichloride Aluminium blister with 14 tablets, in a cardboard box containing 10 blisters (140 tablets).

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

January 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## **16. Contact details**

Marketing authorisation holders <and contact details to report suspected adverse reactions>:

WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG  
Siemensstr. 14  
30827 Garbsen  
Lower Saxony  
Germany

Manufacturer responsible for batch release:

Artesan Pharma GmbH & Co.KG  
Wendlandstr. 1  
29439 Lüchow  
Germany

<Local representatives< and contact details to report suspected adverse reactions>:>

## **17. Other information**

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.

Propentofylline may increase willingness to exercise and exercise tolerance, particularly in older dogs.

Approved 12 January 2023

