1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitofyllin 100 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substance: Propentofylline 100.00 mg/tablet

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Film Coating:	
Titanium Dioxide, E 171	0.43 mg/tablet
Ferric Oxide, yellow, E 172	0.15 mg/tablet
Hypromellose	
Macrogol 6000	
Talc	
Core:	
Lactose monohydrate	
Maize Starch	
Crospovidone	
Talc	
Silicia, Colloidal Anhydrous	
Magnesium Stearate	

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. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Refer to section 3.7.
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.

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.
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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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

Body weight (kg)	**Tablets**		**Daily total tablets**	**Daily total dose (mg/kg)**
	am	**pm**		
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.
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.

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

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

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 ionotropic 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.

4.3 Pharmacokinetics

After oral administration propentofylline is fast and completely absorbed and quickly distributed in the tissues. Given orally to dogs, maximum plasma levels are reached already after 15 minutes.
The half-life is about 30 minutes and the bioavailability for the parent substance amounts to about 30%. There are a number of effective metabolites and the biotransformation takes place mainly in the liver. Propentofylline is excreted in the form of its metabolites between 80-90% via the kidneys. The rest is eliminated with the faeces. There is no accumulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

Shelf life of divided tablet portions: 72 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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.

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 <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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DE:
WDT-Wirtschaftsgenossenschaft deutscher Tierärzte eG

UK:
Animalcare Ltd

7. MARKETING AUTHORISATION NUMBER(S)

DE: 401573.01.00
AT: 8-01072
BE: BE-V418546
FR: FR/V/6132491 0/2012
IE: 10660/002/002
LU: V/925/12/05/1182
ES: 2510 ESP
PT: 451/02/12DFVPT
NL: 109550
HU: 3138/1/12 (56 tablets) 3138/2/12 (140 tablets)
IT: 104402/033 (56 tablets) 104402/045 (140 tablets)
NI: 10347/3000

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 22 February 2012

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

10. 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.