[Version 9,10/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitofyllin 50 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substance: Propentofylline 50.00 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	0.215 mg/tablet
Ferric Oxide, yellow, E 172	0.075 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 "50" 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 2.5 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, divided into two 3-5 mg/kg doses as follows:

Body weight (kg)	**Tablets**		**Daily total tablets**	**Daily total dose (mg/kg)**
	am	**pm**		
2.5 - 4 kg	1/4	1/4	½	6.3 - 10.0
5 - 7 kg	½	½	1	7.1 - 10.0
8 - 9 kg	3/4	3/4	1½	8.3 - 9.4
10 - 15 kg	1	1	2	6.7 - 10.0

16 - 25 kg	1½	1½	3	6.0 - 9.4
26 - 33 kg	2	2	4	6.1 - 7.7

To ensure administration of the correct dose, the body weight of the animal should be determined before treatment.
Dogs of more than 20 kg can be given Vitofyllin 100 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 in 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	401573.00.00
AT	8-01071
BE	BE-V418537
FR	FR/V/8463495 9/2012
IE	10660/002/001
LU	V/925/12/05/1181
ES	2509 ESP
PT	451/01/12DFVPT
NL	109549
HU	3137/1/12 (56 tablets) 3137/2/12 (140 tablets)
IT	104402/019 (56 tablets) 104402/021 (140 tablets)
NI	10347/3001

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.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitofyllin 50 mg film-coated tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 50 mg of Propentofylline.

3. PACKAGE SIZE

56 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

DE:
WDT-Wirtschaftsgenossenschaft deutscher Tierärzte eG

UK:
Animalcare Ltd

14. MARKETING AUTHORISATION NUMBERS

DE: 401573.00.00
AT: 8-01071
BE: BE-V418537
FR: FR/V/8463495 9/2012
IE: 10660/002/001
LU: V/925/12/05/1181
ES: 2509 ESP
PT: 451/01/12DFVPT
NL: 109549
HU: 3137/1/12 (56 tablets) 3137/2/12 (140 tablets)
IT: 104402/019 (56 tablets) 104402/021 (140 tablets)
NI: 10347/3001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitofyllin 50 mg film-coated tablets for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Propentofylline 50.00 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 50 mg film-coated tablets for dogs

2. Composition

Active substance:
Each tablet contains 50 mg of propentofylline.

Excipients:

Ferric Oxide, yellow, (E172)	0.075 mg/tablet
Titanium Dioxide, (E171)	0.215 mg/tablet

Film-coated tablets.
Yellow, round, convex tablets with cross breakline tab on one side and imprinting “50” 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 2.5 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:

Body weight (kg)	Tablets		Daily total tablets	Daily total dose (mg/kg)
	am	pm		
2.5 - 4 kg	¼	¼	½	6.3 - 10.0
5 - 7 kg	½	½	1	7.1 - 10.0
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10 - 15 kg	1	1	2	6.7 - 10.0
16 - 25 kg	1½	1½	3	6.0 - 9.4
26 - 33 kg	2	2	4	6.1 - 7.7

To ensure administration of the correct dose, the body weight of the animal should be determined before treatment.
Dogs of more than 20 kg can be given Vitofyllin 100 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

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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

DD/MM/YYYY
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>:
DE:
WDT-Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstraße 14
30827 Garbsen, Germany
UK:
Animalcare Ltd
10 Great North Way
York Business Park
Nether Poppleton
York
YO26 6RB, UK

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 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.