Vitofyllin 50mg, Vitofyllin 100mg

Animalcare Limited,

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1. Name of the veterinary medicinal product

Vitofyllin 50mg film-coated tablets for dogs

Vitofyllin 100mg film-coated tablets for dogs

2. Qualitative and quantitative composition

	50mg Tablet	100mg Tablet
Active substance:		
Propentofylline	50.0mg	100.0mg
Excipients:		
Ferric Oxide, yellow, (E172)	0.075mg	0.150mg
Titanium Dioxide, (E171)	0.215 mg	0.430mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablets.

Yellow, round, convex tablets with cross-snap tab on one and imprinting "50" or "100" on the other side.

The tablets can be divided into equal halves and quarters.

4. Clinical particulars

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Refer to section 4.7

Do not use in dogs weighing less than 2.5 kg.

Do not use in cases of hypersensitivity to the active substance and/or to any of the other ingredients of the product.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

On rare occasions, allergic skin reactions, vomiting and cardiac disturbances have been reported. In these cases, the treatment should be stopped.

4.7 Use during pregnancy and lactation

Do not use in pregnant or lactating bitches or breeding animals 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

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

Vitofyllin 50mg Tablets

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
8 - 9 kg	¾	¾	1 ½	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

Vitofyllin 100mg Tablets

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

More accurate dosing may be achieved by using either quarters of the 100mg tablets or a combination of 100mg and 50mg 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Excitation tachycardia, hypotension, reddening

of mucous membranes and vomiting.
The withdrawal of the treatment leads to a spontaneous remission of these signs.

5. Pharmacological properties

Pharmacotherapeutic group: peripheral vasodilator; purine derivatives; propentofylline
ATCvet code: QC04AD90

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 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.

5.2 Pharmacokinetic particulars

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-time is about 30 minutes and the bioavailability for the mother 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 form of its metabolites in 80-90% via the kidneys. The rest is eliminated with the faeces. There is no accumulation.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose monohydrate
Maize Starch
Crospovidone
Talc
Silica, Colloidal Anhydrous
Magnesium Stearate
Film Coating:
Titanium Dioxide, E171
Ferric Oxide, yellow, E 172
Hypromellose
Macrogol 6000
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Unused divided tablets should be returned to the blister pack and any divided tablet portions remaining after 72 hours should be discarded.

6.4. Special precautions for storage

Store in the original package (blister) and keep the blister packs in the outer carton and store in a dry place. Divided tablets should be stored in the blister pack.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Animalcare Limited
Common Road,
Dunnington,
York, YO19 5RU
UK

8. Marketing authorisation number(s)

See below

9. Date of first authorisation/renewal of the authorisation

2nd May 2012

Vitofyllin 50mg

UK only	IE only
POM-V	POM
To be supplied only on veterinary prescription	Prescription Only Medicine
Vm: 10347/4032	VPA: 10778/005/001

Vitofyllin 100mg

UK only	IE only
POM-V	POM
To be supplied only on veterinary prescription	Prescription Only Medicine
Vm: 10347/4033	VPA: 10778/005/002