

vitofyllin[®] 100mg

Film-coated tablets for dogs

Propentofylline

Statement of the active substances and other ingredients

Active substance:

Each tablet contains 100mg of propentofylline.

Excipients:

Ferric Oxide, yellow, (E 172)

0.150mg/tablet

Titanium Dioxide, (E171)

0.430mg/tablet

Pharmaceutical Form

Film-coated tablets.

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

The tablets can be divided into equal halves and quarters.

Indications

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

Contraindications

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

Do not use in dogs weighing less than 5kg.

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

Adverse reactions

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species

Dogs

Dosage and method of administration

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

Body weight (kg)	Tablets		Daily total tablets	Daily total dose (mg/kg)
	am	pm		
20 - 33	1	1	2	6.0 - 10.0
34 - 49	1½	1½	3	6.1 - 8.8
50 - 66	2	2	4	6.1 - 8.0
67 - 83	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 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.

Special storage precautions

Keep out of the reach and sight of children.

Store in the original package (blister) and keep the blister packs in the outer carton and store in a dry place. Unused divided tablets should be returned to the blister pack and any divided tablet portions remaining after 72 hours should be discarded.

Do not use after the expiry date stated on the carton and blister after "EXP".

Special warnings

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.

Overdose:

Excitation tachycardia, hypotension, reddening of mucous membranes and vomiting.

The withdrawal of the treatment leads to a spontaneous remission of these signs.

Special precautions for the disposal of unused product or waste material, if any

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

Date on which the package leaflet was last approved: February 2012

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.

For animal treatment only.

Pack sizes

Polyvinylchloride - polyvinylidene dichloride /aluminium blister with 14 tablets, in a cardboard box containing 4 blisters (56 tablets) or 10 blisters (140 tablets).

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Animalcare Ltd, 10 Great North Way, York, YO26 6RB, UK

Manufacturer for the batch release:

Artesan Pharma GmbH & Co. KG, Wendlandstraße 1, D - 29439 Lüchow, Germany

UK only:

Vm 10347/4033

POM-V

To be supplied only on veterinary prescription

IE only:

VPA 10778/005/002

POM

Prescription only medicine