

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitofyllin 100 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Propentofylline 100.00 mg/tablet

Excipients:

Ferric Oxide, yellow, (E 172) 0.150 mg/tablet

Titanium Dioxide, (E171) 0.430 mg/tablet

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

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

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

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 5 kg.

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

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.
In the event of accidental ingestion of the tablets, seek medical advice immediately and show the package leaflet or label to the physician.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

On rare occasions, (more than 1 but less than 10 animals in 10,000 animals treated), allergic skin reactions, vomiting and cardiac disturbances have been reported. In these cases, the treatment should be stopped.

4.7 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.

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

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

| <u>Body weight (kg)</u> | <u>Tablets</u> | | <u>Daily total tablets</u> | <u>Daily total 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 |

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.

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.

4.11 Withdrawal period(s)

Not applicable

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 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.

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-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.

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: 5 years

Shelf-life of divided tablet portions: 72 hours

6.4 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.

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).

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

Not all pack sizes may be marketed.

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

April 2017

Approved: 28 April 2017

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending to the right.