1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canergy 100 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Propentofylline 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Maize starch
Crospovidone (type A)
Purified talc
Colloidal anhydrous silica
Calcium behenate
Yeast, deactivated
Artificial beef flavour

Light brown with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side.
The tablets 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

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.
See also section 3.7.

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.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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.
Any unused tablet portion should be returned to the open blister and inserted back into the carton to be used for the next administration.

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 reaction [a] Cardiac disorder [a] Vomiting [a]

[a] 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and/or lactation.

Pregnancy and lactation:
Use in pregnant or lactating bitches or breeding animals is not recommended.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

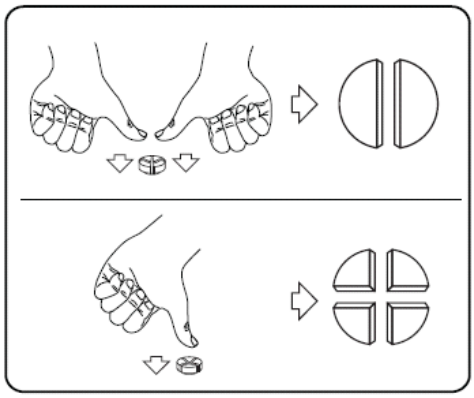
To ensure a correct dosage, body weight should be determined as accurately as possible before treatment. The basic dosage is 6 – 10 mg propentofylline/kg bodyweight daily, divided into two doses as follows:

	100 mg Tablets			
Body weight (kg)	**Morning**	**Evening**	**Daily total tablets**	**Daily total dose (mg/kg)**
5 kg – 8 kg			½	6.25 – 10.0
>8 kg – 10 kg			¾	7.5 – 9.4
>10 kg – 15 kg			1	6.7 – 10.0
>15 kg – 25 kg			1 ½	6.0 – 10.0
>25 kg – 33 kg			2	6.1 – 8.0
>33 kg – 49 kg			3	6.1 – 9.1
>49 kg – 66 kg			4	6.1 – 8.2
>66 kg – 83 kg			5	6.0 – 7.6

= ¼ Tablet = ½ Tablet = ¾ Tablet = 1 Tablet

The tablets can be administered directly in the mouth, 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.

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halves: press down with your thumbs on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

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 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.

4.3 Pharmacokinetics

After oral administration propentofylline is rapidly and completely absorbed and quickly distributed in the tissues. Maximum plasma levels are reached by 15 minutes following oral dosing in dogs.
The half-life is about 30 minutes and the bioavailability for the parent compound is approximately 30 %. There are a number of effective metabolites and the biotransformation takes place mainly in the liver. 80 - 90 % of propentofylline is excreted in the form of metabolites via the kidneys. The rest is eliminated in faeces. There is no bioaccumulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 4 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Any unused tablet portion should be returned to the open blister and inserted back into the carton to be used for the next administration.

5.4 Nature and composition of immediate packaging

Aluminium - PA/ALU/PVC blister.
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 25 or 50 blisters of 10 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/016/001

8. DATE OF FIRST AUTHORISATION

29/05/2015

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

07/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).