Summary of Product Characteristics

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:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
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.

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

Do not use in dogs weighing less than 5 kg.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
See also section 4.7.

4.4 Special warnings for each target species

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.
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 the event of accidental ingestion of the tablets, 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.

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 veterinary medicinal product has not been established during pregnancy and/or lactation. Use in pregnant or lactating bitches or breeding animals is therefore not recommended.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

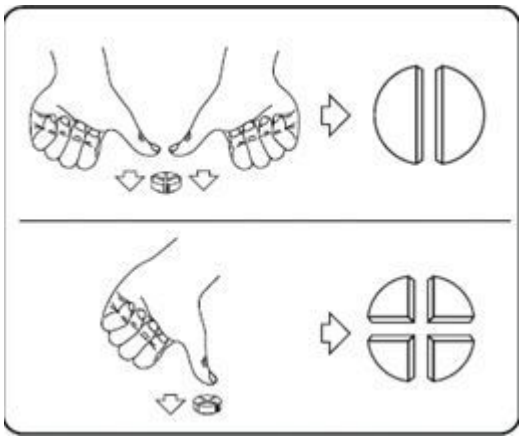
To ensure administration of the correct dose, the body weight of the animal should be determined before treatment. The basic dosage is 6-10 mg propentofylline/kg bodyweight daily, divided into two doses as follows:

	100 mg Tablets			
Body weight (kg)	**Morning**	**Evening**	**Daily total tablets**	**Daily total dose (mg/kg)**
5 kg – 8 kg	¼	¼	½	6.25 – 10.0
>8 kg – 10 kg	½	¼	¾	7.5 – 9.4
>10 kg – 15 kg	½	½	1	6.7 – 10.0
>15 kg – 25 kg	¾	¾	1 ½	6.0 – 10.0
>25 kg – 33 kg	1	1	2	6.1 – 8.0
>33 kg – 49 kg	1 ½	1 ½	3	6.1 – 9.1
>49 kg – 66 kg	2	2	4	6.1 – 8.2
>66 kg – 83 kg	2 ½	2 ½	5	6.0 – 7.6

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

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 or IMMUNOLOGICAL 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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize starch
Crospovidone
Talc

Silica colloidal anhydrous
Calcium Behenate
Yeast, deactivated
Artificial beef flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

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

6.4 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.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10475/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 May 2015
Date of last renewal: 03 April 2020

10 DATE OF REVISION OF THE TEXT

April 2020