SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canergy 100 mg tablets for dogs (AT, BE, CY, CZ, DE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, NL, PT, RO, SI, SK, UK)
Canergy vet. 100 mg tablets for dogs (DK, EE, FI, IS, NO, PL, SE)

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 interaction

None known.

4.9 Amounts to be administered and administration route

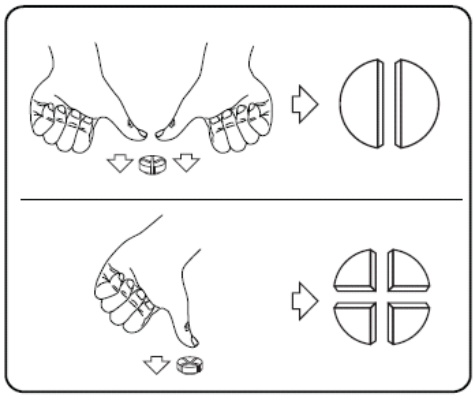
To ensure administration of the correct dose, the body weight of the animal should be determined before treatment. The basic dosage is 6-10 mg propentofylline/kg bodyweight daily, divided into two doses as follows:

	100 mg Tablets			
Body weight (kg)	**Morning**	**Evening**	**Daily total tablets**	**Daily total dose (mg/kg)**
5 kg – 8 kg			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.

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 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 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

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canergy 100 mg tablets for dogs (AT, BE, CY, CZ, DE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, NL, PT, RO, SI, SK, UK)
Canergy vet. 100 mg tablets for dogs (DK, EE, FI, IS, NO, PL, SE)
propentofylline

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Propentofylline 100 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 250, 500 tablets

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of divided tablets after first opening the immediate packaging: 4 days.

11. SPECIAL 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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Alu- PA/Alu/PVC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canergy 100 mg tablets for dogs (AT, BE, CY, CZ, DE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, NL, PT, RO, SI, SK, UK)
Canergy vet. 100 mg tablets for dogs (DK, EE, FI, IS, NO, PL, SE)
propentofylline

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

Canergy 100 mg tablets for dogs (AT, BE, CY, CZ, DE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, NL, PT, RO, SI, SK, UK)
Canergy vet. 100 mg tablets for dogs (DK, EE, FI, IS, NO, PL, SE)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Artesan Pharma GmbH & Co KG
Wendlandstrasse 1
29439 Lüchow
Germany

Lelypharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

Genera d.d.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canergy 100 mg tablets for dogs
propentofylline

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:
Active substance: Propentofylline 100 mg

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. INDICATION(S)

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

5. 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..
Please also see the section on use during pregnancy and lactation.

6. ADVERSE REACTIONS

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.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

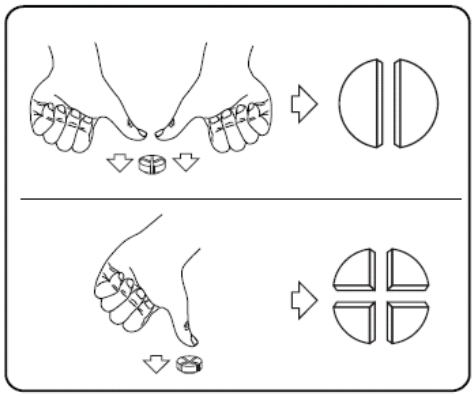
The basic dosage is 6-10 mg propentofylline per kg bodyweight daily, divided into two doses as follows:

	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

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf life of divided tablets after first opening the immediate packaging: 4 days.
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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and/or lactation. The use in pregnant or lactating bitches or breeding animals is therefore not recommended.

Overdose (symptoms, emergency procedures, antidotes):
Excitation tachycardia, hypotension, reddening of mucous membranes and vomiting
The withdrawal of the treatment leads to a spontaneous remission of these signs.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

xxxxxxxxxxxxxxx

15. OTHER INFORMATION

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.