ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabam 500 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Cefalexin (as cefalexin monohydrate) 500 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Potato Starch
Silica, colloidal hydrated
Yeast (dried)
Chicken Flavour
Magnesium stearate

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

- Respiratory tract infections, especially bronchopneumonia, caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli* and *Klebsiella* spp.
- Urinary tract infections caused by *Escherichia coli*, *Proteus* spp. and *Staphylococcus* spp.
- Skin infections caused by *Staphylococcus* spp.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to other cephalosporins, to other substances of the β-lactam group or to any of the excipients.
Do not use in known cases of resistance to cephalosporins or penicillins.
Do not use in rabbits, guinea pigs, hamsters and gerbils.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Due to the likely variability (time, geographical) in the occurrence of cefalexin resistant bacteria, bacteriological sampling and susceptibility testing are recommended.

The veterinary medicinal product should only be used based on susceptibility testing of the bacteria isolated from the animals. If this is not possible, therapy should be based on local epidemiological information.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness of treatment with other beta-lactam antibiotics due to the potential for cross-resistance.

In case of chronic renal insufficiency the dose should be reduced or the dosage interval should be increased.

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:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross-reactions to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this veterinary medicinal product if you know you are sensitised or if you have been advised not to be in contact with such substances.

Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions. If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

To avoid accidental ingestion of the veterinary medicinal product by a child, divided or unused tablets should be returned to the open blister pocket and placed back in the outer carton.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[a]
Very rare	Vomiting [b], Diarrhoea [b], Lethargy

(<1 animal / 10,000 animals treated, including isolated reports):	

[a] The treatment should be discontinued.
[b] In case of recurrence, the treatment should be discontinued and the advice of the attending veterinarian sought.

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

Pregnancy and lactation:
Laboratory studies in rats and mice have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product in dogs has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

In order to ensure efficacy, the veterinary medicinal product should not be used in combination with bacteriostatic antibiotics (macrolides, sulfonamides and tetracyclines). Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.

3.9 Administration routes and dosage

For oral use.
The recommended dose is 15-30 mg cefalexin per kg body weight twice a day, during at least 5 consecutive days. An extended course of treatment may be prescribed by the responsible veterinarian in cases of, for example, urinary tract infections or bacterial dermatitis.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

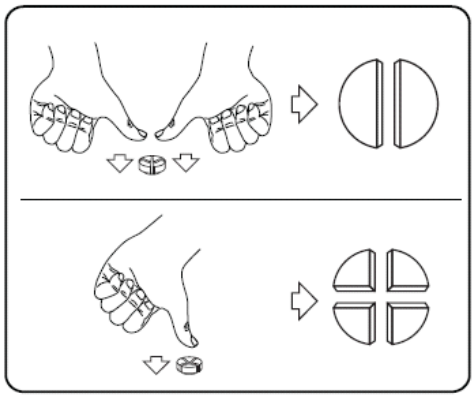
The following table is intended as a guide to dispensing the veterinary medicinal product at a dose rate of 15 mg cefalexine per kg body weight twice a day.

ADMINISTRATION TWICE DAILY					
Body weight	**Dose mg**	**Cefabam 50 mg**	**Cefabam 250 mg**	**Cefabam 500 mg**	**Cefabam 1000 mg**
>0.5 kg – 0.8 kg	12.5		-	-	-
>0.8 kg – 1.6 kg	25		-	-	-
>1.6 kg – 2.5 kg	37.5		-	-	-
>2.5 kg – 3.3 kg	50		-	-	-
>3.3 kg – 5 kg	75		-	-	-
>5 kg – 6.6 kg	100		-	-	-
>6.6 kg – 8 kg	125			-	-
>8 kg – 10 kg	150		-	-	-
>10 kg – 12.5 kg	188	-		-	-

>12.5 kg – 16.6 kg	250	-	⊕	◗	-
>16.6 kg – 20 kg	313		⊕ ◸		
>20 kg – 25 kg	375	-	⊕ ◗	-	-
>25 kg – 29 kg	438	-	⊕ ◕	-	-
>29 kg – 33 kg	500	-	⊕ ⊕	⊕	◗
>33 kg – 41 kg	625	-	-	⊕ ◸	-
>41 kg – 50 kg	750	-	-	⊕ ◗	◕
>50 kg – 58 kg	875	-	-	⊕ ◕	-
>58 kg – 66 kg	1000	-	-	⊕ ⊕	⊕
>66 kg – 83kg	1250	-	-	-	⊕ ◸

◸ = ¼ Tablet ◗ = ½ Tablet ◕ = ¾ Tablet ⊕ = 1 Tablet

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.



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)

No other known side effects than those under section 3.6.
In the event of overdose, treatment should be symptomatic.

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

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DB01

4.2 Pharmacodynamics

The mechanism of action of cephalosporins resembles that of the penicillins, in particular that of ampicillin (common beta-lactam ring). Cephalosporins especially has a time-dependent bactericidal effect in dividing bacteria. They bind irreversibly with 'penicillin-binding proteins (PBPs'), enzymes that are needed for the cross-coupling of peptidoglycan strands during the synthesis of the bacterial cell wall. This interferes with the cross-linkage of peptidoglycan chains necessary for bacterial cell strength and rigidity, and results in abnormal cell growth and cell lysis.
Cephalexin is active against both gram positive and some gram negative bacteria.

The following CLSI cephalothin veterinary breakpoints are available for dogs (CLSI VET01S ed. 5, November 2020).
Cephalothin can be used as indicator of first generation cephalosporins.
Skin and soft tissue infections:

Bacterial species	Susceptible	Resistant
Staphylococcus aureus and *Staphylococcus pseudintermedius*	≤ 2 µg/ml	≥ 4 µg/ml
Streptococcus spp and *E. coli*	≤ 2 µg/ml	≥ 8 µg/ml

Urinary tract infections:

Bacterial species	Susceptible	Resistant
E. coli, Klebsiella pneumoniae and *Proteus mirabilis*	≤ 16 µg/ml	≥ 32 µg/ml

As with penicillins resistance to cefalexin may be due to one of the following mechanisms of resistance: the production of various beta-lactamases, encoded on plasmids or not encoded or by multistage mutations. In the first case, there is almost always cross-resistance with ampicillin; in the other cases there is partial or complete cross-resistance to all penicillins and cephalosporins. Conversely, methicillin-resistant staphylococci are unsusceptible to cephalosporins.

4.3 Pharmacokinetics

After administration of cephalexin monohydrate cephalexin rapidly and almost completely absorbed in the gastrointestinal tract. Absorption is delayed by food (lower blood levels). Protein plasma binding is approximately 20%.
Single oral administration of 20 mg of cephalexin per kg body weight to dogs resulted in a T_{max} of approximately 1-1.5 hours, a C_{max} in plasma of about 15 µg/ml and an elimination half-life of about 2 hours (bioavailability = 75% -80%). The volume of distribution is 1.62 l/kg.
After absorption, cephalexin is well distributed in the extracellular fluids of the body, however, the passage of biological membranes is limited. The concentrations of cephalexin are highest in the kidneys (urine), and bile, followed by the liver, lungs, heart, skeletal muscle and spleen.
Hardly any metabolism occurs in the liver. Elimination is almost entirely via the kidneys by tubular excretion and glomerular filtration. Cephalexin is also excreted in the bile in a concentration that is equal or somewhat higher than in the blood.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life of divided tablets: 4 days.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister.
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 25 blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister 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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabam 500 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Cefalexin (as cefalexin monohydrate) 500 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Use divided tablets within 4 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium-PVC/PE/PVDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefabam

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Use divided tablets within 4 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

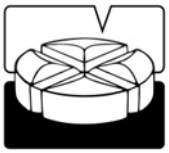
Cefabam 500 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Cefalexin (as cefalexin monohydrate) 500 mg

Light brown with brown spots, round and convex, flavoured tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.



3. Target species

Dogs.

4. Indications for use

For the treatment of:
- Respiratory tract infections, especially bronchopneumonia, caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli* and *Klebsiella* spp.
- Urinary tract infections caused by *Escherichia coli*, *Proteus* spp. and *Staphylococcus* spp.
- Skin infections caused by *Staphylococcus* spp.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to other cephalosporins, to other substances of the β-lactam group or to any of the excipients.
Do not use in known cases of resistance to cephalosporins or penicillins
Do not use in rabbits, guinea pigs, hamsters and gerbils.

6. Special warnings

Special precautions for safe use in the target species:
Due to the likely variability (time, geographical) in the occurrence of cefalexin resistant bacteria, bacteriological sampling and susceptibility testing are recommended.
The veterinary medicinal product should only be used based on susceptibility testing of the bacteria isolated from the animals. If this is not possible, therapy should be based on local epidemiological information.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Use of the veterinary medicinal product deviating from the instructions given in this package leaflet may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness of treatment with other beta-lactam antibiotics due to the potential for cross-resistance. In case of chronic renal insufficiency the dose should be reduced or the dosage interval should be increased. 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:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross-reactions to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this veterinary medicinal product if you know you are sensitised or if you have been advised not to be in contact with such substances.

Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions. If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

To avoid accidental ingestion of the veterinary medicinal product by a child, divided or unused tablets should be returned to the open blister pocket and placed back in the outer carton.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation:
Laboratory studies in rats and mice have not produced any evidence of effects harmful to the foetus. The safety of the veterinary medicinal product in dogs has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
In order to ensure efficacy, the veterinary medicinal product should not be used in combination with bacteriostatic (suppressing bacterial growth) antibiotics (macrolides, sulfonamides and tetracyclines). Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance the risks of kidney damage.

Overdose:
No other known side effects than those under section ‘Adverse events’.
In the event of overdose, treatment should be symptomatic.

<Special restrictions for use and special conditions for use:>

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction (allergic reaction)[a]
Very rare	Vomiting [b], Diarrhoea [b],

(<1 animal / 10,000 animals treated, including isolated reports):	Lethargy

[a] The treatment should be discontinued.
[b] In case of recurrence, the treatment should be discontinued and the advice of the attending veterinarian sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For oral use.
The recommended dose is 15-30 mg cefalexin per kg body weight twice a day, during at least 5 consecutive days. An extended course of treatment may be prescribed by the responsible veterinarian in cases of, for example, urinary tract infections or skin inflammations caused by bacteria.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The following table is intended as a guide to dispensing the veterinary medicinal product at a dose rate of 15 mg cefalexine per kg body weight twice a day.

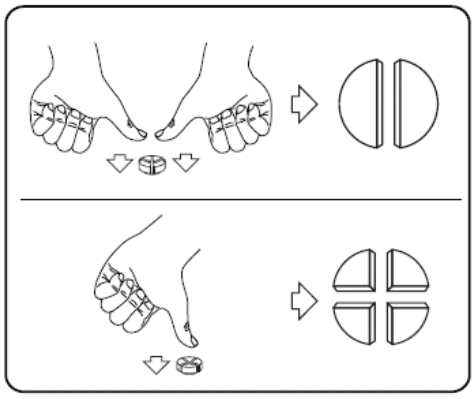
ADMINISTRATION TWICE DAILY					
Body weight	**Dose mg**	**Cefabam 50 mg**	**Cefabam 250 mg**	**Cefabam 500 mg**	**Cefabam 1000 mg**
>0.5 kg – 0.8 kg	12.5	¼	-	-	-
>0.8 kg – 1.6 kg	25	½	-	-	-
>1.6 kg – 2.5 kg	37.5	¾	-	-	-
>2.5 kg – 3.3 kg	50	1	-	-	-
>3.3 kg – 5 kg	75	1 ½	-	-	-
>5 kg – 6.6 kg	100	2	-	-	-
>6.6 kg – 8 kg	125	2 ½	½	-	-
>8 kg – 10 kg	150	3	-	-	-
>10 kg – 12.5 kg	188	-	¾	-	-
>12.5 kg – 16.6 kg	250	-	1	½	-
>16.6 kg – 20 kg	313		1 ¼		
>20 kg – 25 kg	375	-	1 ½	-	-
>25 kg – 29 kg	438	-	1 ¾	-	-
>29 kg – 33 kg	500	-	2	1	½
>33 kg – 41 kg	625	-	-	1 ¼	-
>41 kg – 50 kg	750	-	-	1 ½	¾

>50 kg – 58 kg	875	-	-		-
>58 kg – 66 kg	1000	-	-		
>66 kg – 83kg	1250	-	-	-	

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

9. Advice on correct administration

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.



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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Shelf life of divided tablets: 4 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp.
The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems.These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 25 blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

<Local representatives <and contact details to report suspected adverse reactions>:>

<17. Other information>