

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocefavet 750 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Cefalexin (as cefalexin monohydrate) 750 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Cellulose, microcrystalline	
Povidone K30	
Sodium starch glycolate (type A)	
Maize starch	
Meat flavour	
Magnesium stearate	

Off-white to light brown with brown spots, round and convex tablet with a cross-shaped break line on one side. Tablets can be divided into 2 or 4 equal parts. The tablet has an approximately diameter of 16 mm.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the treatment of:

- urinary tract infections caused by *Escherichia coli*, *Proteus mirabilis* and *Staphylococcus aureus*;
- skin infections caused by *Staphylococcus* spp;
- respiratory tract infections caused by *Pasteurella multocida*.

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 rabbits, guinea pigs, hamsters and gerbils.

3.4 Special warnings

Do not use in known cases of resistance to cephalosporins or penicillins.

Cross-resistance has been shown between cefalexin and other beta-lactams antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to beta-lactams because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product should only be used based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced or the dosage interval should be increased, antimicrobials known to be nephrotoxic should not be administered concurrently and the product should be used only according to a risk-benefit assessment by the responsible veterinarian.

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

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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. People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product.

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. Wash hands after use.

This veterinary medicinal product may be harmful after accidental ingestion. To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space, inserted back into the outer packaging and the veterinary medicinal product should be kept in a safe place out of sight and reach of children.

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare	Hypersensitivity reaction*
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(1 to 10 animals / 10,000 animals treated)	
Very rare (<1 animal / 10,000 animals treated)	Lethargy
Undetermined frequency (cannot be estimated from the available data)	Vomiting, nausea, diarrhoea

*in case of a hypersensitivity reaction, the treatment should be discontinued.

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 in dogs has not been established during pregnancy and lactation.

Pregnancy and lactation

Laboratory studies in rats and mice have not produced any evidence of teratogenic effects.

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
















Oral use.

15 mg cefalexin per kg body weight, twice daily, for 5 consecutive days. An extended course of treatment may be prescribed by the responsible veterinarian. In severe or acute cases the dosage can be doubled only according to the benefit-risk assessment by the responsible veterinarian.

To ensure a correct dosage body weight should be determined as accurately as possible.

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

15 mg/kg	Number of tablets, twice a day			
Body weight(kg)	Cefalexin 50 mg	Cefalexin 75 mg	Cefalexin 375 mg	Cefalexin 750 mg
1 - 1.25	☐ Or ☐			
1.25 -2.5	⊕ Or ⊕			
2.5 -3.75	⊕ Or ⊕			

3.75 -5		Or			
5 -6.25				Or	
6.25 - 12.5					 Or 
12.5 - 18.75					
18.75 - 25				Or	
25 - 31.25					
31.25 - 37.5				Or	
37.5 - 50					
50 -62.5					
62.5 - 75					

Due to the cross-shaped score line, the tablets can be divided into two equal parts (375 mg of cefalexin) or four equal parts (187.5 mg of cefalexin). Divided tablets should be used at next administration.

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)

In case of overdose, no other undesirable effects are known other than the side effects mentioned in 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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DB01

4.2 Pharmacodynamics

Cefalexin is a β -lactam antibiotic from the first generation cephalosporins. It acts by inhibiting the synthesis of bacterial cell walls in the same way as penicillin. Cephalosporins reduce the production of bacterial cell membranes leading to abnormal cell elongation, spheroplast formation or osmotic lysis. In general, cephalosporins have a bactericidal effect. Cephalosporins have varying degrees of resistance to beta-lactamase produced by staphylococci and Gram-negative bacteria. Staphylococci sensitive to methicillin or oxacillin, regardless of penicillinase production, can be considered sensitive to oral cephalosporins.

The following veterinary breakpoints from CLSI VET01SEd7E (2024) are available for dogs:

Source of infection	Pathogen	Breakpoints: MIC ($\mu\text{g/ml}$)		
		Susceptible	Intermediate	Resistant
skin and soft tissue	<i>Staphylococcus aureus</i>	≤ 2		≥ 4
	<i>Staphylococcus pseudintermedius</i>	≤ 2		≥ 4
urinary tract	<i>Escherichia coli</i>	≤ 16		≥ 32
	<i>Proteus mirabilis</i>	≤ 16		≥ 32

There are three basic mechanisms of resistance to cephalosporins: PBP (penicillin-binding protein) modification (related to *mec* genes), reduced permeability and increased efflux, and enzymatic inactivation by beta-lactamases (associated with AmpC-genes or extended spectrum beta-lactamases associated with SHV, TEM and CTX-M genes).

Cross-resistance has been shown between cefalexin and other β -lactams. See also section 3.4. Special warnings.

4.3 Pharmacokinetics

Cefalexin is quickly and almost completely absorbed into the blood. The plasma peak concentration (C_{max}) is between 19-32 micrograms/ml. The time required to reach C_{max} (T_{max}) is then between 1-2 hours and the elimination half-life ($t_{1/2}$) is between 1.7-2.8 hours when dogs were administered 25 mg cefalexin/kg body weight orally. The bioavailability of cefalexin is approximately 75% after oral administration. A small portion (18%) of cefalexin is bound to serum proteins in dogs. Cefalexin is mainly excreted via the kidneys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Any remaining tablet portions should be given at the next administration.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Primary packaging:

PVC-Aluminium-oriented polyamide (oPA) / Aluminium blister, containing 10 tablets.

Secondary packaging:

Cardboard box of 1 blister of 10 tablets

Cardboard box of 3 blisters of 10 tablets

Cardboard box of 10 blisters of 10 tablets

Cardboard box of 25 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

Axience

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocefavet 750 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:

Cefalexin (as cefalexin monohydrate) 750 mg

3. PACKAGE SIZE

10 tablets
30 tablets
100 tablets
250 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Axience

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocefavet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains

Cefalexin (as cefalexin monohydrate) 750 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Biocefavet 750 mg chewable tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Cefalexin (as cefalexin monohydrate) 750 mg

Off-white to light brown with brown spots, round and convex tablet with a cross-shaped break line on one side. Tablets can be divided into 2 or 4 equal parts. The tablet has an approximately diameter of 16 mm.

3. Target species

Dogs.

4. Indications for use

For the treatment of:

- urinary tract infections caused by *Escherichia coli*, *Proteus mirabilis* and *Staphylococcus aureus*;
- skin infections caused by *Staphylococcus* spp;
- respiratory tract infections caused by *Pasteurella multocida*.

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 rabbits, guinea pigs, hamsters and gerbils.

6. Special warnings

Special warnings:

Do not use in known cases of resistance to cephalosporins or penicillins.

Cross-resistance has been shown between cefalexin and other beta-lactams antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to beta-lactams because its effectiveness may be reduced.

Special precautions for safe use in the target species:

The veterinary medicinal product should only be used based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced or the dosage interval should be increased, antimicrobials known to be nephrotoxic should not be administered concurrently and the product should be used only according to a risk-benefit assessment by the responsible veterinarian.

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

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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.

People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product.

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. Wash hands after use.

This veterinary medicinal product may be harmful after accidental ingestion.

To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space, inserted back into the outer packaging and the veterinary medicinal product should be kept in a safe place out of sight and reach of children.

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

Pregnancy and lactation:

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

Laboratory studies in rats and mice have not produced any evidence of teratogenic effects.

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 antibiotics (macrolides, sulfonamides and tetracyclines). Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.

Overdose:

In case of overdose, no other undesirable effects are known other than the side effects mentioned under section Adverse events.

In the event of overdose, treatment should be symptomatic.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated)	Hypersensitivity reaction*
Very rare (<1 animal / 10,000 animals treated)	Lethargy

Undetermined frequency (cannot be estimated from the available data)	Vomiting, nausea, diarrhoea
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* in case of a hypersensitivity reaction, the treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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:




























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

Oral use.

15 mg cefalexin per kg body weight, twice daily, for 5 consecutive days. An extended course of treatment may be prescribed by the responsible veterinarian. In severe or acute cases the dosage can be doubled only according to the benefit-risk assessment by the responsible veterinarian.

To ensure a correct dosage body weight should be determined as accurately as possible.

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

15 mg/kg	Number of tablets, twice a day			
Body weight(kg)	Cefalexin 50 mg	Cefalexin 75 mg	Cefalexin 375 mg	Cefalexin 750 mg
1 - 1.25	 Or 			
1.25 -2.5	 Or 			
2.5 -3.75	 Or 			
3.75 -5	  Or 			
5 -6.25		  Or 		
6.25 - 12.5			 Or 	
12.5 - 18.75				
18.75 - 25			 Or 	
25 - 31.25			 	
31.25 - 37.5			  Or 	
37.5 - 50				
50 -62.5				 
62.5 - 75				 

Due to the cross-shaped score line, the tablets can be divided into two equal parts (375 mg of cefalexin) or four equal parts (187.5 mg of cefalexin). Divided tablets should be used at next administration.

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.

9. Advice on correct administration

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Any remaining tablet portions should be given at the next administration.

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

Primary packaging:

PVC-Aluminium-oriented polyamide (oPA) / Aluminium blister, containing 10 tablets.

Secondary packaging:

Cardboard box of 1 blister of 10 tablets

Cardboard box of 3 blisters of 10 tablets

Cardboard box of 10 blisters of 10 tablets

Cardboard box of 25 blisters of 10 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

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

Axience

Tour Essor -14 Rue Scandicci

93500 Pantin

France

Manufacturer responsible for batch release

Lelypharma B.V.

Zuiveringsweg 42

8243 PZ Lelystad

The Netherlands

<only in case marketing authorisation holder is also the local contact to report suspected adverse reactions: Tel: +33141832310>

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

<17. Other information>

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