[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen 50mg/ml Powder for Oral Suspension for Dogs up to 20kg and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of reconstituted oral suspension contains:

Active substance:
Cefalexin (as cefalexin monohydrate) 50 mg
(equivalent to cefalexin monohydrate 52.6 mg)

One bottle with 66.6 g of powder for oral suspension contains:

Active substance:
Cefalexin 5,000.0 mg
(equivalent to cefalexin monohydrate 5,259.1 mg)

One bottle with 40.0 g of powder for oral suspension contains:

Active substance:
Cefalexin 3,000.0 mg
(equivalent to cefalexin monohydrate 3,155.4 mg)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension.
White-coloured powder

Reconstituted suspension: red-coloured suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs up to 20kg and cats

4.2 Indications for use, specifying the target species

DOGS: For the treatment of infections of the respiratory system, urogenital system and skin, localised infections in soft tissue and gastrointestinal infections caused by bacteria susceptible to cefalexin.

CATS: For the treatment of infections of the respiratory system, urogenital system and skin and localised infections in soft tissue caused by bacteria susceptible to cefalexin.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance, to other cephalosporins, to other substances of the beta-lactam group or to any of the excipients.

Do not use in rabbits, gerbils, guinea pigs and hamsters.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Wherever possible, use of the product should be based on susceptibility testing of the bacteria isolated from the animal and take into account official and local antimicrobial policies.

Deviating from the instructions given in the SPC when using the product may increase the prevalence of bacteria resistant to cefalexin and may also decrease the effectiveness of other beta-lactam antimicrobial treatments, due to the potential for cross-resistance.

Do not administer in cases of known resistance to cephalosporins and penicillin.

As with other antibiotics which are excreted mainly by the kidneys, systemic accumulation may occur when renal function is impaired. In case of known renal insufficiency the dose should be reduced and substances known to be nephrotoxic should not be administered concurrently.

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 and take care to avoid prolonged skin contact. When preparing the reconstituted product, ensure lid is correctly closed before shaking to mix product. Take care when loading the syringe to avoid spillage.

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.

Accidental ingestion may result in gastrointestinal disturbances. In order to reduce the risk of accidental ingestion by children, close the bottle immediately after use. Do not leave a syringe containing suspension unattended and ensure syringe is out of sight and reach of children at all times. In order to prevent children from getting access to the used syringe, store the bottle and syringe in the outer carton.

When stored in the refrigerator, the oral suspension should be kept in a safe place out of sight and reach of children.

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

Do not smoke, eat or drink while handling the medication.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In products containing cephalexin, mild and transient vomiting and diarrhoea have been observed very commonly in cats even at the lowest recommended dosage regime. The symptoms were reversible in most cats without symptomatic treatment. Vomiting has been observed occasionally in dogs treated with products containing cefalexin. As with other antibiotics, diarrhoea can occur. In case of recurring vomiting and/or diarrhoea, the treatment should be discontinued and the advice of the attending veterinarian sought.

In very rare cases, nausea may occur following administration of the product.

In rare cases hypersensitivity can occur. In cases of hypersensitivity reaction the treatment should be discontinued.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy or lactation

Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic, or embryotoxic effects.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Cephalexin crosses the placental barrier in pregnant animals.

4.8 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.

Concurrent use of first generation cephalosporins with polypeptide antibiotics, aminoglycosides or some diuretics such as furosemide can enhance nephrotoxicity risks.

4.9 Amounts to be administered and administration route

Oral use.

The recommended dose is 15 mg of cefalexin per kg of body weight (0.3 ml of reconstituted product per kg of body weight), twice a day. In severe or acute conditions the dose may be doubled to 30 mg/kg (0.6 ml/kg) twice daily.

The product must be administered for a minimum of 5 days.
- 14 days in cases of urinary tract infection,
- At least 15 days in cases of superficial infectious dermatitis,
- At least 28 days in cases of deep infectious dermatitis.

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

To facilitate the dosage and the administration, the syringe present in the package can be used.

The veterinary medicinal product can be added to food if necessary.

Prior to addition of water for reconstitution, the bottle should be inverted and tapped to loosen the powder before adding water.
Water is added to the respective fill line on the bottle. The bottle is then closed, inverted and vigorously shaken for 60 seconds. The level of solution will drop slightly therefore continue adding water up to the fill line marked on the bottle label prior to filling the dosing syringe.

After reconstitution, the volume of red-coloured suspension is 100 ml for the bottle containing 66.6 g of powder and 60 ml for the bottle containing 40.0 g of powder.

Shake vigorously before each use of the product for at least 60 seconds.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Concerning acute toxicity, an LD_{50} > 0.5 g/kg has been recorded following oral administration of cefalexin to cats and dogs. The administration of cefalexin has been shown to produce no serious side effects at several times the recommended dose rate.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other beta-lactam antibacterials. First-generation cephalosporins
ATCvet Code: QJ01DB01

5.1 Pharmacodynamic properties

Cefalexin is a broad spectrum cephalosporin antibiotic with bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria.

Cefalexin is a semi-synthetic bactericidal broad spectrum antibiotic belonging to the cephalosporin group which acts by interfering with bacterial cell wall formation. This bactericidal activity is mediated by drug binding to bacterial enzymes known as penicillin binding proteins (PBPs). Such enzymes are located on the inner membrane of the cell wall and their transpeptidase activity is required for the terminal stages of assembling this essential structure of the bacterial cell. Inactivation of PBPs interferes with the cross-linkage of peptidoglycan chains necessary for bacterial cell wall strength and rigidity. The bactericidal effect of cefalexin is mainly time dependent.

Cefalexin is resistant to the action of staphylococcal penicillinase and is therefore active against the strains of *Staphylococcus aureus* that are not susceptible to penicillin (or related antibiotics such as ampicillin or amoxycillin) because of production of penicillinase.

Cefalexin is also active against the majority of ampicillin-resistant *E.coli*.

The following micro-organisms have been shown to be susceptible to Cefalexin *in vitro*:
C*orynebacterium* spp, *Staphylococcus* spp (including penicillin-resistant strains), *Streptococcus* spp, *Escherichia coli*, *Moraxella* spp, *Pasteurella multocida*.

The following breakpoints are recommended by the CLSI (2018) in dogs for *E.coli* and *Staphylococcus* spp:

MIC (µg/mL)	Interpretation
≤2	Susceptible
4	Intermediate
≥8	Resistant

Recent surveillance data from France, analysing bacteria isolated from dogs and cats in 2018 demonstrates the following susceptibility of key pathogens to cephalexin:

Pathogen	Source	Total isolates (N)	% Susceptibility
E. coli	Canine (kidney & urinary tract pathology)	1,517	71
	Canine (skin & soft tissue infections)	150	68
	Canine (otitis)	232	76
	Feline (all pathologies)	1,327	78
	Feline (kidney & urinary tract pathology)	989	76
Proteus mirabilis	Canine (all pathologies)	1,229	79
Pasteurella	Canine (all pathologies)	383	94
	Feline (respiratory pathology)	177	94

For cefalexin, susceptible ≤ 8 mg/L and Resistant > 32 mg/L. Based on the recommendations of the French Antibiogram Comity (CA-SFM 2019)

Resistance to cefalexin may be due to one of the following mechanisms of resistance. Firstly, the production of various extended-spectrum beta-lactamases (ESBLs), that inactivate the antibiotic, is the most prevalent mechanism among gram-negative bacteria. Secondly, a decreased affinity of the PBPs (penicillin-binding proteins) for beta-lactam drugs is frequently involved for beta-lactam resistant gram-positive bacteria. Staphylococci commonly harbour the methicillin resistance gene mecA encoding a penicillin binding protein (PBP2a) with low affinity for beta-lactams. Lastly, efflux pumps, extruding the antibiotic from the bacterial cell, and structural changes in porins, reducing passive diffusion of the drug through the cell wall, may contribute to improve the resistant phenotype of a bacterium.

Well-known cross-resistance (involving the same resistance mechanism) exists between antibiotics belonging to the beta-lactam group due to structural similarities. It occurs with beta-lactamase enzymes, structural changes in porins or variations in efflux pumps. Co-resistance (different resistance mechanisms involved) has been described in *E.coli* due to a plasmid harbouring various resistance genes.

5.2 Pharmacokinetic particulars

Cefalexin is rapidly and almost completely absorbed in the gastrointestinal tract following oral administration. Cefalexin binds to a limited extent (10-20%) to plasma proteins.
Cefalexin is poorly metabolised. Elimination of the microbiologically active form is almost entirely via the kidneys by tubular excretion and glomerular filtration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Laurilsulfate
Allura Red AC (E129)
Methylcellulose
Dimethicone
Xanthan gum

Starch, pre-gelatinised
Imitation guarana flavour
Sucrose

6.2 Major incompatibilities

None known.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 28 days.

6.4. Special precautions for storage

Do not open the bottle until the product requires reconstitution.
Store below 25° C.
After reconstitution, store the oral suspension in a refrigerator (2° C - 8° C)
Do not freeze the reconstituted suspension.
Keep the bottle in the outer carton in order to protect from light.
Keep the bottle tightly closed.

6.5 Nature and composition of immediate packaging

High density polyethylene bottle and polypropylene child-resistant screw cap with liner.
Dosing syringe with 0.1 ml graduations in polyethylene and 5 ml polystyrene piston.

Package size:
Carton box with 1 bottle containing 66.6 g of powder providing 100 ml of suspension after reconstitution and 1 syringe of 5 ml
Carton box with 1 bottle containing 40.0 g of powder providing 60 ml of suspension after reconstitution and 1 syringe of 5 ml

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

I.C.F. srl
Via G.B. Benzoni
50 - 26020 Palazzo Pignano
Cremona
Italy

8. MARKETING AUTHORISATION NUMBER(S)

<To be allocated nationally post-authorisation>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY
Date of last renewal: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

<To be completed nationally post-authorisation>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen 50 mg/ml Powder for Oral Suspension for Dogs up to 20kg and Cats
Cefalexin

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

Powder for oral suspension.

4. PACKAGE SIZE

100 ml bottle
60 ml bottle

5. TARGET SPECIES

Dogs up to 20 kg and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for instructions for reconstitution and disposal.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

10. EXPIRY DATE

<EXP {month/year}>
Once reconstituted, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Store below 25° C.
Do not open the bottle until the product requires reconstitution.
After reconstitution, store the oral suspension in a refrigerator (2° C - 8° C).
Do not freeze the reconstituted suspension.
Keep the bottle in the outer carton in order to protect from light.
Keep the bottle tightly closed.

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

I.C.F. srl
Via G.B. Benzoni
50 - 26020 Palazzo Pignano
Cremona
Italy

16. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally following approval>

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

100 ML HIGH DENSITY POLYETHYLENE BOTTLE WITH SCREW CAP
60 ML HIGH DENSITY POLYETHYLENE BOTTLE WITH SCREW CAP

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen 50mg/ml Powder for Oral Suspension for Dogs up to 20kg and Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

66.6g of powder/100ml suspension
40.0g of powder/60ml suspension

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

<EXP {month/year}>
After reconstitution, store the oral suspension in a refrigerator (2° C - 8° C) and use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Tsefalen 50mg/ml Powder for Oral Suspension for Dogs up to 20kg and Cats

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

Marketing authorisation holder:
I.C.F. srl
Via G.B. Benzoni
50 - 26020 Palazzo Pignano
Cremona
Italy

Manufacturer responsible for batch release:
ACS Dobfar S.p.A.
Via Laurentina km 24,730 - 00071
Pomezia (RM)
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen 50 mg/ml Powder for Oral Suspension for Dogs up to 20kg and Cats
Cefalexin

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

Powder for oral suspension.

White-coloured powder.
Reconstituted suspension: red-coloured suspension.

One ml of reconstituted oral suspension contains:

Active substance:
Cefalexin (as cefalexin monohydrate) 50 mg
(equivalent to cefalexin monohydrate 52.6 mg)

One bottle with 66.6 g of powder for oral suspension contains:

Active substance:
Cefalexin 5,000.0 mg
(equivalent to 5,259.1 mg cefalexin monohydrate)

One bottle with 40.0 g of powder for oral suspension contains:

Active substance:
Cefalexin 3,000.0 mg
(equivalent to 3,155.4 mg cefalexin monohydrate)

4. INDICATION(S)

DOGS: For the treatment of infections of the respiratory system, urogenital system and skin, localised infections in soft tissue and gastrointestinal infections caused by bacteria susceptible to cefalexin.

CATS: For the treatment of infections of the respiratory system, urogenital system and skin, and localised infections in soft tissue caused by bacteria susceptible to cefalexin.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance, to other cephalosporins, to other substances of the beta-lactam group or to any of the excipients.

Do not use in rabbits, gerbils, guinea pigs and hamsters.

6. ADVERSE REACTIONS

In products containing cephalexin, mild and transient vomiting and diarrhoea have been observed very commonly in cats even at the lowest recommended dosage regime. The symptoms were reversible in most cats without symptomatic treatment. Vomiting has been observed occasionally in dogs treated with products containing cefalexin. As with other antibiotics, diarrhoea can occur. In case of recurring vomiting and/or diarrhoea, the treatment should be discontinued and the advice of the attending veterinarian sought.

In very rare cases, nausea may occur following administration of the product.

In rare cases hypersensitivity can occur. In cases of hypersensitivity reaction the treatment should be discontinued.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs up to 20 kg and cats.

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

Oral use.

The recommended dose is 15 mg of cefalexin per kg of body weight (0.3 ml of reconstituted product per kg of body weight), twice a day. In severe or acute conditions the dose may be doubled to 30 mg/kg (0.6 ml/kg) twice daily.

The product must be administered for a minimum of 5 days:

- 14 days in cases of urinary tract infection,
- At least 15 days in cases of superficial infectious dermatitis,
- At least 28 days in cases of deep infectious dermatitis.

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

9. ADVICE ON CORRECT ADMINISTRATION

To facilitate the dosage and the administration, the syringe present in the package can be used. The veterinary medicinal product can be added to food if necessary.

Instructions for preparation of the suspension:
Prior to addition of water for reconstitution, the bottle should be inverted and tapped to loosen the powder before adding water.

Water is added to the respective fill line on the bottle. Replace and tighten the bottle cap and shake vigorously for 60 seconds until all the powder is in suspension. The level of solution will drop slightly therefore continue adding water up to the fill line marked on the bottle label. If prepared according to these instructions, each millilitre will contain 50 mg of cefalexin.

After reconstitution, the volume of red-coloured suspension is 100 ml for the bottle containing 66.6 g of powder and 60 ml for the bottle containing 40.0 g of powder.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not open the bottle until the product requires reconstitution.
Store below 25° C.
After reconstitution, store the oral suspension in a refrigerator (2° C - 8° C).
Do not freeze the reconstituted suspension.
Keep the bottle in the outer carton in order to protect from light.
Keep the bottle tightly closed.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after {EXP/abbreviation used for expiry date}.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

Wherever possible, use of the product should be based on susceptibility testing of the bacteria isolated from the animal and take into account official and local antimicrobial policies.

Use of the product deviating from the instructions given in the package leaflet, and those given by the responsible veterinarian, when using the product, may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness of other beta-lactam antimicrobial treatments, due to the potential for cross-resistance.

Do not administer in cases of known resistance to cephalosporins and penicillin.

As with other antibiotics which are excreted mainly by the kidneys, systemic accumulation may occur when renal function is impaired. In case of known renal insufficiency the dose should be reduced and substances known to be nephrotoxic should not be administered concurrently.

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 and take care to avoid prolonged skin contact. When preparing the reconstituted product, ensure lid is correctly closed before shaking to mix product. Take care when loading the syringe to avoid spillage.

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.

Accidental ingestion may result in gastrointestinal disturbances. In order to reduce the risk of accidental ingestion by children, close the bottle immediately after use. Do not leave a syringe containing suspension unattended and ensure syringe is out of sight and reach of children at all times. In order to prevent children from getting access to the used syringe, store the bottle and syringe in the outer carton.

When stored in the refrigerator, the oral suspension should be kept in a safe place out of sight and reach of children.

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

Do not smoke, eat or drink while handling the medication.

Wash hands after use.

Pregnancy and lactation:

Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic, or embryotoxic effects.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Cephalexin crosses the placental barrier in pregnant animals.

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.

Concurrent use of first generation cephalosporins with polypeptide antibiotics, aminoglycosides or some diuretics such as furosemide can enhance nephrotoxicity risks.

Overdose (symptoms, emergency procedures, antidotes):

The administration of cefalexin has been shown to produce no serious side effects at several times the recommended dose rate.

Incompatibilities:

None known.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Medicines should not be disposed of via wastewater or household waste.
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

<To be completed nationally following approval>

<15. OTHER INFORMATION>

Carton box with 1 bottle containing 66.6 g of powder providing 100 ml of suspension after reconstitution and 1 syringe of 5 ml.
Carton box with 1 bottle containing 40.0 g of powder providing 60 ml of suspension after reconstitution and 1 syringe of 5 ml.

Not all pack sizes may be marketed.

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