

[Version 8.1, 01/2017]

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen 1000 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substance:

Cefalexin (as cefalexin monohydrate) 1000 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets

Orange coloured oblong film-coated tablets, with a break-line on one side. Engraved with U60 on the other side.

The tablets can be divided into two equalparts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of infections of the respiratory system, urogenital system and skin, localised infections in soft tissue and gastrointestinal infections caused by cefalexin-sensitive bacteria.

4.3 Contraindications

Do not use in cases of known 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, 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. Therefore, deviation from the instructions must only be undertaken according to a risk/benefit assessment by the responsible veterinarian.

Do not administer in cases of known resistance to cephalosporin 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 antimicrobials 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 sensitisation (allergy) following injection, inhalation, ingestion, or skin contact. Sensitivity to penicillins may lead to cross-sensitivity to cephalosporins 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.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

In rare cases hypersensitivity can occur. In cases of hypersensitivity reactions 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 and lactation

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

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

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 twice a day (i.e. equivalent to one tablet twice a day for a dog weighing 66 kg). In severe or acute conditions the dose may be doubled to 30 mg/kg twice daily.

The following is a guide for the use of the product:

TSEFALEN 1000mg tablets

Bodyweight min kg	Bodyweight max kg	Number of tablets per dose*
41.0	66.0	1
66.1	80.0	1.5

**Dose to be given twice per day*

Animals weighing more than 81 kg bodyweight should be administered an appropriate combination of tablets according to bodyweight.

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.

Any increase in dose or duration of treatment should be accordingly to a benefit/risk assessment by the responsible veterinarian (e.g. chronic pyoderma).

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

The veterinary medicinal product can be given as whole tablets, or crushed and added to food if necessary.

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

Concerning acute toxicity, an LD50 > 0.5 g/kg has been recorded following oral administration in 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

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 sensitive to penicillin (or related antibiotics such as ampicillin or amoxicillin) 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 sensitive to Cefalexin *in vitro*: *Corynebacterium* spp, *Staphylococcus* spp (including penicillin-resistant strains), *Streptococcus* spp, *Escherichia coli*, *Moraxella* spp, *Pasteurella multocida*.

MIC data collected for cefalexin in canine isolates from the European Union (EU) (Stegmann *et al.* 2006)

Bacterial species/group and origin	No. isolates	MIC50	MIC90
<i>Staphylococcus pseudintermedius</i> (EU)	270	1	2
<i>Staphylococcus aureus</i> (EU)	36	2	8
Coagulase-negative staphylococci (EU)	21	1	8
Coagulase-positive staphylococci (EU)	24	1	2
β -haemolytic streptococci (EU)	86	<0.5	2
<i>Enterococcus</i> spp. (EU)	331	>64	>64
<i>Pasteurella multocida</i> (EU)	193	4	4
<i>Escherichia coli</i> (EU)	260	8	16
<i>Proteus</i> spp. (EU)	71	16	16
<i>Klebsiella</i> spp. (EU)	11	4	4
<i>Enterobacter</i> spp. (EU)	39	8	>64

The three basic mechanisms of resistance to cephalosporins result from reduced permeability, enzymatic inactivation, or absence of specific penicillin-binding proteins.

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. After oral administration of 15 mg/kg in tablets, peak blood concentration (C_{max} =15 μ g/ml) is usually reached between 1 and 2 hours (T_{max} =90 min).

Bioavailability is nearly 100% of the administered dose (AUC 6279 μ g min / ml). Cefalexin does not undergo biotransformation processes that are of pharmacokinetic significance.

The elimination half-life of cefalexin is about 1.5 hours ($t_{1/2}$ = 90 min).

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

Titanium dioxide (E171)
Iron oxide yellow (E172)
Iron oxide red (E172)
Povidone K-90
Sodium Starch Glycolate Type A
Magnesium stearate
Glycerol
Talc
Hypromellose

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after dividing the tablet into two: 48 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Return any halved tablet to the blister pack.

6.5 Nature and composition of immediate packaging

Carton box containing 1 PVC/Aluminium blister pack of 8 tablets.
Carton box containing 4 PVC/Aluminium blister pack of 8 tablets, with a total of 32 tablets.
Carton box containing 13 PVC/Aluminium blister pack of 8 tablets, with a total of 104 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ICF Srl Industria Chimica Fine
Via G.B. Benzoni, 50
26020 Palazzo Pignano – Cremona
Italy
Tel +39.0373.982024
Fax +39.0373.982025
email: icf.pet@icfsrl.it

8. MARKETING AUTHORISATION NUMBER(S)

<Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the DC/MR phase.>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed in accordance with national requirements after conclusion of the DC/MR phase.>

10. DATE OF REVISION OF THE TEXT

<To be completed in accordance with national requirements after conclusion of the DC/MR phase.>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen 1000 mg film-coated tablets for dogs
FI: Tsefalen vet 1000 mg film-coated tablets for dogs

Cefalexin (as cefalexin monohydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains 1000 mg of cefalexin (as cefalexin monohydrate).

3. PHARMACEUTICAL FORM

Film-coated tablets.

4. PACKAGE SIZE

8 tablets
32 tablets
104 tablets

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

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}

11. SPECIAL STORAGE CONDITIONS

Return any halved tablet to the blister pack and use within 48 hours.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

ICF Srl Industria Chimica Fine
Via G.B. Benzoni, 50
26020 Palazzo Pignano – Cremona
Italy
Tel +39.0373.982024
Fax +39.0373.982025
email: icf.pet@icfsrl.it

16. MARKETING AUTHORISATION NUMBER(S)

Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the DC/MR phase.

17. MANUFACTURER’S BATCH NUMBER

Lot {BN}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen 1000 mg film-coated tablets for dogs
FI: Tsefalen vet 1000 mg film-coated tablets for dogs

Cefalexin (as cefalexin monohydrate)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

ICF
Via G.B. Benzoni, 50
26020 Palazzo Pignano - Cremona
Italy

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Tsefalen (Falakef) 1000 mg film-coated tablets for dogs
FI: Tsefalen (Falakef) vet 1000 mg film-coated tablets for dogs

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. s.r.l. Industria Chimica Fine
Via G.B. Benzoni, 50.
26020 Palazzo Pignano (CR)
Italy
Tel +39.0373.982024
Fax +39.0373.982025
email: icf.pet@icfsrl.it

Manufacturer for the batch release:

ACS DOBFAR S.p.A.
via Laurentina Km 24,730
00071 Pomezia (RM)
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen (Falakef) 1000 mg film-coated tablets for dogs
FI: Tsefalen (Falakef) vet 1000 mg film-coated tablets for dogs

Cefalexin (as cefalexin monohydrate)

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

Each film-coated tablet contains 1000 mg of cefalexin (as cefalexin monohydrate).

Orange coloured oblong film-coated tablets, with a break-line on one side. Engraved with U60 on the other side. The tablets can be divided into two equal parts.

4. INDICATION(S)

For the treatment of infections of the respiratory system, urogenital system and skin, localised infections in soft tissue and gastrointestinal infections caused by cefalexin-sensitive bacteria.

5. CONTRAINDICATIONS

Do not use in cases of known 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, gerbils, guinea pigs and hamsters.

6. ADVERSE REACTIONS

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

In rare cases hypersensitivity can occur. In cases of hypersensitivity reactions 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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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 twice a day (i.e. equivalent to one tablet twice a day for a dog weighing 66 kg). In severe or acute conditions the dose may be doubled to 30 mg/kg twice daily.

The following is a guide for the use of the product:

TSEFALEN 1000mg tablets

Bodyweight min kg	Bodyweight max kg	Number of tablets per dose*
41.0	66.0	1
66.1	80.0	1.5

**Dose to be given twice per day*

Animals weighing more than 51 kg bodyweight should be administered an appropriate combination of tablets according to bodyweight.

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.

Any increase in dose or duration of treatment should be accordingly to a benefit/risk assessment by the responsible veterinarian (e.g. chronic pyoderma).

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

9. ADVICE ON CORRECT ADMINISTRATION

Tsefalen film-coated tablets can be given as whole tablets, or crushed and added to food if necessary.

10. WITHDRAWAL PERIOD(S)

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.

Return any halved tablet to the blister pack and use within 48 hours.

Do not use after the expiry date stated on the label.

12. SPECIAL WARNINGS

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 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.

Do not administer in cases of known resistance to cephalosporin 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 antimicrobials 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 sensitisation (allergy) following injection, inhalation, ingestion, or skin contact. Hypersensitivity to penicillins may lead to cross-sensitivity to cephalosporins 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.

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 teratogenic, foetotoxic, or maternotoxic effects.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly 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.

Concurrent use of first generation cephalosporins with aminoglycoside antibiotics 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.

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

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2019

15. OTHER INFORMATION

For animal treatment only.

8 tablets

32 tablets

104 tablets

Not all pack sizes may be marketed.