

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tsefalen 500 mg film-coated tablets for dogs

Cefalexin (as cefalexin monohydrate)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each film-coated tablet contains 500 mg of cefalexin (as cefalexin monohydrate).

**3. PHARMACEUTICAL FORM**

Film-coated tablets.

**4. PACKAGE SIZE**

12 tablets

36 tablets

108 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. Read the package leaflet before use.

**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)**

Vm 39896/4000

**17. MANUFACTURER’S BATCH NUMBER**

Lot {BN}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTER**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Tsefalen 500 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) 500 film-coated tablets for dogs  
FI: Tsefalen (Falakef) vet 500 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) 500 mg film-coated tablets for dogs.  
FI: Tsefalen (Falakef) vet 500 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 500 mg of cefalexin (as cefalexin monohydrate).

Orange coloured oblong film-coated tablets, with a break-line on one side. Engraved with GP4 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  $\beta$ -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, vomit 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/kg of cefalexin per kg of body weight twice a day (i.e. equivalent to 1 tablet twice a day for a dog weighing 33 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 500mg tablets

Bodyweight min kg	Bodyweight max kg	Number of tablets per dose*
10.0	16.5	0.5
16.6	33.0	1
33.1	40.0	1.5

*\*Dose to be given twice per day*

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 WARNING(S)

### 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. 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.



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.

12 tablets

36 *tablets*

108 tablets

Not all pack sizes may be marketed.



Approved: 26 April 2019