

**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

**2. STATEMENT OF ACTIVE SUBSTANCES**

50 mg/ml cefalexin (as cefalexin monohydrate)

**3. PACKAGE SIZE**

100 ml  
60 ml

**4. TARGET SPECIES**

Dogs up to 20 kg and cats.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use within 28 days.

**9. SPECIAL STORAGE PRECAUTIONS**

Store below 25° C.  
Do not open the bottle until the veterinary medicinal 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.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

User warnings

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

**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**

Nextmune Italy S.R.L.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 58047/4002

**15. BATCH NUMBER**

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

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Cefalexin 50 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use within 28 days and store in a refrigerator.

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 2. Composition

Each ml after reconstitution contains:

#### Active substance:

Cefalexin (as cefalexin monohydrate) 50 mg  
(equivalent to cefalexin monohydrate 52.6 mg)

#### Excipients:

Allura Red AC (E129) 0.10 mg

White-coloured powder.

Reconstituted suspension: red-coloured suspension.

### 3. Target species

Dogs up to 20 kg and cats.

### 4. Indications for use

**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 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. Special warnings

#### Special warnings:

None.

#### Special precautions for safe use in the target species:

Wherever possible, use of the veterinary medicinal 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 package leaflet when using the veterinary medicinal 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 veterinary medicinal product, ensure lid is correctly closed before shaking to mix veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

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:

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

Special restrictions for use and special conditions for use:

Major incompatibilities:

None known.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

**7. Adverse events**

Cats:

Very common (1 to 10 animals / 10 animals treated)	Vomiting <sup>1,2</sup> , Diarrhoea <sup>1,2</sup>
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction <sup>3</sup> .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Nausea.

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction <sup>3</sup> .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Nausea, vomiting <sup>2</sup> , diarrhoea <sup>2</sup> .

<sup>1</sup>Mild and transient, at the lowest recommended dosage regime. Symptoms were reversible in most cats without symptomatic treatment.

<sup>2</sup> In case of recurrence, the treatment should be discontinued and the advice of the attending veterinarian sought

<sup>3</sup> In cases of hypersensitivity reactions 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 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.

The recommended dose is 15 mg of cefalexin per kg of body weight (0.3 ml of reconstituted veterinary medicinal 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 veterinary medicinal 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.

## **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. 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. 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. Shake vigorously before each use of the veterinary medicinal product for at least 60 seconds.

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not open the bottle until the veterinary medicinal 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. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 28 days.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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**

Vm 58047/4002

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.

#### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

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

Nextmune Italy S.R.L.  
Via G.B. Benzoni 50  
26020 Palazzo Pignano (CR)  
Italy  
Phone +39 0373 982024  
E-mail: [info.it@nextmune.com](mailto:info.it@nextmune.com)

Manufacturer responsible for batch release:

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

#### **17. Other information**

*Gavin Hall*  
Approved: 09 April 2025