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 1000 mg film-coated tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Cefalexin 1000 mg

3. PACKAGE SIZE

8 tablets
32 tablets
104 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 48 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

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 NUMBER

Vm 58047/4001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tsefalen

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cefalexin 1000 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 48 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tsefalen 1000 mg film-coated tablets for dogs

2. Composition

Each film-coated tablet contains:

Active substance:
Cefalexin 1000 mg
(equivalent to 1051,9 mg cefalexin monohydrate)

Excipients:
Iron oxide yellow (E172) 0.16 mg
Iron oxide red (E172) 0.02 mg

Orange coloured oblong film-coated tablets, with a break-line on one side. Engraved with GP4 on the other side.

3. Target species

Dogs.

4. Indications for use

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 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 SPC 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. 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.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:

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

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:
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.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
None known.

7. Adverse events

Dogs:

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

[1] 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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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 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 veterinary medicinal product:

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 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.

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

9. Advice on correct administration

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

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

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 temperature 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.

Shelf life after first opening the immediate packaging: 48 hours.
Return any halved tablet to the blister pack.

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 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 58047/4001

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.

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.

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

Manufacturer responsible for batch release:

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

17. Other information

Approved 10 March 2025
Gavin Hall