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

NEXTMUNE Italy S.R.L.
Via G.B. Benzoni 50
26020 Palazzo Pignano - Cremona
Italy

16. MARKETING AUTHORISATION NUMBER(S)

Vm 58047/4002

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:
NEXTMUNE Italy S.R.L.
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 - 0071
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

May 2023

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.

Approved 26 May 2023