**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lexylan 180 mg/ml suspension for injection for cattle, dogs and cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**

Cefalexin (as cefalexin sodium): 180 mg

**Excipient(s):**

| **Qualitative composition of excipients and other constituents** |
|---|
| Castor oil, hydrogenated |
| Triglycerides, medium-chain |

White to slightly yellow suspension for injection.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, dogs, cats

### 3.2 Indications for use for each target species

Cattle:
For the treatment of metritis, interdigital dermatitis, wound infections and abcesses and septicemic mastitis in addition of an intramammary therapy.

Dogs:
For the treatment of infections of the respiratory tract, the uro-genital system, the skin, soft tissues and the gastro-intestinal system.

Cats:
For the treatment of infections of the respiratory tract, the uro-genital system, the skin and soft tissues.

### 3.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporins and other Beta-lactam antibiotics or to any of the excipients.
Do not use in cases of impaired renal function, given the risk of cumulation.
The veterinary medicinal product is not suited for intravenous or intrathecal injection.

### 3.4 Special warnings

Cross-resistance has been shown between cefalexin and other β-lactams. Use of the cefalexin should be carefully considered when susceptibility testing has shown resistance to other β-lactams because its effectiveness may be reduced.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

Shake the vial to achieve full resuspension before use.
Susceptibility of pathogens can change in time. An antibiogram can be useful before treatment.

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies. An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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 penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this 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 with breathing, are more serious symptoms and require urgent medical attention. Wash hands after use.

To the user:
This veterinary medicinal product contains a synthetic vegetable oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains a synthetic vegetable oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse events

Cattle, dogs and cats:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Hypersensitivity |
| Undetermined frequency | - Injection site inflammation<br>- Unnecessary cumulation |

| | |
|---|---|
| (cannot be estimated from the available data): | |

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy:
Laboratory studies in laboratory animals have not produced any evidence of foetotoxic effects. The safety of cefalexin has not been established in pregnant animals.

Lactation:
The safety of cefalexin has not been established in lactating animals.

### 3.8 Interaction with other medicinal products and other forms of interaction

An antagonism exists with bacteriostatic antibiotics like macrolides, tetracyclins and chloramphenicol. Concomitant use of other potential nephrotoxic product e.g. aminoglycosides, polymyxin antibiotics, methoxyflurane or concomitant use with diuretics (furosemide) can increase the nephrotoxic effects.

### 3.9 Administration routes and dosage

For intramuscular or subcutaneous use in dogs and cats.
For intramuscular use in cattle.

Shake the vial to achieve full resuspension before use.

In dogs and cats:
The recommended dose is 10 mg of cefalexin per kg of bodyweight (corresponding to 0.55ml of the product per 10kg of bodyweight) administered subcutaneously or intramuscularly once a day for 5 days.

In cattle:

The recommended dose is 7 mg of cefalexin per kg of bodyweight (corresponding to 0.39ml of the product per 10kg of bodyweight) administered intramuscularly once a day for 5 days.

Do not broach the 100 ml vial more than 25 times and the 250 ml vial more than 50 times.

The maximal volume to be administered per injection site is 20ml.

Hydrolysis of cefalexin occurs in the presence of water. It is therefore important to use a dry and clean syringe to avoid that potential water drops in the syringe would contaminate the remaining content of the flask.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Cefalexin has low toxicity.

Administration of 100, 200 and 400 mg/kg/day to dogs for 1 year only resulted in salivation in the two highest dose groups and eventually vomiting in all three groups.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Cattle:
Meat and offal: 12 days.
Milk: zero hours.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:
QJ01DB01

### 4.2 Pharmacodynamics

Cefalexin is a cephalosporin of the first generation and belongs to the beta-lactam antibiotics.
The bactericidal effect of cefalexin is based on interference with the cell membrane synthesis by inactivation of transpeptidase.
Cefalexin is mainly active against Gram-positive organisms:

- *Staphylococcus spp.* (penicillin-resistant strains included),
- *Streptococcus spp.*
- *Trueperella pyogenes*

The following "Gram-negative" organisms are moderately sensitive:

- *Pasteurella spp.*
- *Escherichia coli*
- *Fusobacterium spp.*

*Pseudomonas spp., Enterobacter spp.* and other *Proteus* are resistant.

There are three basic mechanisms of resistance to cephalosporins: PBP (penicillin-binding protein) reduced affinity (related to *mec* genes located on horizontally mobile Staphylococcal Cassette Chromosome mec SCCmec), reduced permeability and increased efflux, and enzymatic inactivation by betalactamases (associated with AmpC-genes or plasmid mediated extended spectrum beta-lactamases associated with variant of SHV, TEM and CTX-M genes).

Acquired resistances are common for Gram-negative bacteria that produce various types of beta-lactamases notably in *Escherichia coli* where moderate proportion of resistance are observed.
The use of broad-spectrum beta-lactams (such as cefalexin) could lead to the selection of multidrug-resistant bacterial phenotypes (for example, those producing extended-spectrum beta-lactamases [ESBLs]).
Cross-resistance has been shown between cefalexin and other β-lactams. See also 3.4. Special warnings.

### 4.3 Pharmacokinetics

Cefalexin is quickly absorbed after intramuscular or subcutaneous injection. Maximal serum concentrations are achieved within one hour.
Cefalexin has a wide tissue distribution: liver, kidneys, respiratory system and soft tissues.
The elimination half-life is about 3 hours.
Elimination occurs mainly by the kidneys by glomerular filtration and by secretion near the tubuli. A small portion is excreted with the bile. In urine and in the bile, cephalosporin is excreted in unchanged form.
Product-specific pharmacokinetic characteristics are not known.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

### 5.3 Special precautions for storage

Do not store above 30°C.

### 5.4 Nature and composition of immediate packaging

Type II glass vials closed with a fluorinated bromobutyl rubber stopper and sealed with an aluminium cap.

**Package sizes:**

Cardboard box with 1 vial containing 100 ml
Cardboard box with 1 vial containing 250 ml

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

## 7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/308/001-002

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY.

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

# ANNEX II

## OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton box containing one bottle of 100ml or 250ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lexylan 180 mg/ml suspension for injection.

## 2. STATEMENT OF ACTIVE SUBSTANCES

Cefalexin (as cefalexin sodium): 180 mg/ml

## 3. PACKAGE SIZE

100ml
250ml

## 4. TARGET SPECIES

Cattle, dogs, cats

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Cattle: Intramuscular use.
Dogs, cats: Intramuscular or subcutaneous use.

## 7. WITHDRAWAL PERIODS

Cattle:
Meat and offal: 12 days
Milk: zero hours

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use by:

## 9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

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

Read the package leaflet before use.

## 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

Emdoka

## 14. MARKETING AUTHORISATION NUMBERS

EU/2/24/308/001
EU/2/24/308/002

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**One bottle containing 100ml or 250ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lexylan 180 mg/ml suspension for injection.

## 2. STATEMENT OF ACTIVE SUBSTANCES

Cefalexin (as cefalexin sodium): 180 mg/ml

## 3. TARGET SPECIES

Cattle, dogs, cats

## 4. ROUTES OF ADMINISTRATION

Cattle: Intramuscular use.
Dogs, cats: Intramuscular or subcutaneous use.

Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

Cattle:
Meat and offal: 12 days
Milk: zero hours

## 6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use by:

## 7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

## 9. BATCH NUMBER

Lot {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Lexylan 180 mg/ml suspension for injection for cattle, dogs and cats.

## 2. Composition

Each ml contains:

**Active substance:**

Cefalexin (as cefalexin sodium): 180 mg

**Excipient(s):**

| Qualitative composition of excipients and other constituents |
|---|
| Castor oil, hydrogenated |
| Triglycerides, medium-chain |

White to slightly yellow suspension.

## 3. Target species

Cattle, dogs and cats.

## 4. Indications for use

Cattle:
For the treatment of metritis, interdigital dermatitis, wound infections and abcesses and septicemic mastitis in addition of an intramammary therapy.

Dogs:
For the treatment of infections of the respiratory tract, the uro-genital system, the skin, soft tissues and the gastro-intestinal system.

Cats:
For the treatment of infections of the respiratory tract, the uro-genital system, the skin and soft tissues.

## 5. Contraindications

Do not use in cases of hypersensitivity to cephalosporins and other Beta-lactam antibiotics or to any of the excipients.
Do not use in cases of impaired renal function, given the risk of cumulation.
The veterinary medicinal product is not suited for intravenous or intrathecal injection.

## 6. Special warnings

Special warnings:

Cross-resistance has been shown between cefalexin and other β-lactams. Use of the cefalexin should be carefully considered when susceptibility testing has shown resistance to other β-lactams because its effectiveness may be reduced.

Special precautions for safe use in the target species:

Shake the vial to achieve full resuspension before use.
Susceptibility of pathogens can change in time. An antibiogram can be useful before treatment.

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies. An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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 penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this 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 with breathing, are more serious symptoms and require urgent medical attention. Wash hands after use.

To the user:
This veterinary medicinal product contains a synthetic vegetable oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains a synthetic vegetable oil. Even if small amounts have been injected,
accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:
Laboratory studies in laboratory animals have not produced any evidence of foetotoxic effects. The safety of cefalexin has not been established in pregnant animals.

Lactation:
The safety of cefalexin has not been established in lactating animals.

Interaction with other medicinal products and other forms of interaction:
An antagonism exists with bacteriostatic antibiotics like macrolides, tetracyclins and chloramphenicol. Concomitant use of other potential nefrotoxic product eg aminoglycosides, polymyxin antibiotics, methoxyflurane or concomitant use with diuretics (furosemide) can increase the nephrotoxic effects.

Overdose:

Cefalexin has low toxicity.
Administration of 100, 200 and 400 mg/kg/day to dogs for 1 year only resulted in salivation in the two highest dose groups and eventually vomiting in all three groups.

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

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

## 7. Adverse events

Cattle, dogs and cats:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Hypersensitivity |
| Undetermined frequency<br>(cannot be estimated from the available data): | - Injection site inflammation<br>- Unnecessary cumulation |

Reporting adverse events is important. It allows continuous safety monitoring of a 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 or the local representative of 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

For intramuscular or subcutaneous use in dogs and cats.
For intramuscular use in cattle.

In dogs and cats:
The recommended dose is 10 mg of cefalexin per kg of bodyweight (corresponding to 0.55ml of the product per 10kg of bodyweight) administered subcutaneously or intramuscularly once a day for 5 days.

In cattle:

The recommended dose is 7 mg of cefalexin per kg of bodyweight (corresponding to 0.39ml of the product per 10kg of bodyweight) administered intramuscularly once a day for 5 days.

The maximal volume to be administered per injection site is 20ml.

## 9. Advise on correct administration

The veterinary medicinal product is to be administered intramuscularly or subcutaneously.
Hydrolysis of cefalexin occurs in the presence of water. It is therefore important to use a dry and clean syringe to avoid that potential water drops in the syringe would contaminate the remaining content of the flask.
Shake the vial to achieve full resuspension before use.

Do not broach the 100 ml vial more than 25 times and the 250 ml vial more than 50 times.

## 10. Withdrawal periods

Cattle:
Meat and offal: 12 days
Milk: zero hours

## 11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30°C.

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 of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

## 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 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

EU/2/24/308/001-002

Package sizes:
Cardboard box with 1 vial containing 100 ml
Cardboard box with 1 vial containing 250 ml

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder:
Emdoka
John Lijsenstraat 16
2321 Hoogstraten
Belgium

Manufacturer responsible for batch release:
WDT – Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemenstrasse 14
30827 Garbsen
Germany

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**België/Belgique/Belgien**
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