

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

The product is indicated for antibiotic therapy in cattle, cats and dogs. Cefalexin is a broad spectrum cephalosporin antibiotic with bactericidal activity against a wide range of Gram-positive, Gram-negative and anaerobic bacteria. When susceptible organisms are present, the product is indicated in the following instances:

Cattle

For the treatment of metritis, foot and wound infections and abscesses caused by *Micrococcus spp.*, *Streptococcus spp.*, *Escherichia coli.*, *Clostridium spp.*, *Erysipelothrix rhusiopathiae*, *Fusobacterium spp.*, *Pasteurella spp.*, *Peptococcus spp.*, *Peptostreptococcus spp.*, and *Actinomyces bovis*.

For the treatment of septicaemic mastitis to supplement intramammary therapy caused by *Corynebacterium spp.*, *Micrococcus spp.*, *Staphylococcus spp.* (including penicillin-resistant strains), *Streptococcus spp.*, and *Escherichia coli*.

For the treatment of infections caused by *Actinobacillus lignieresii* and *Moraxella spp.*

Dogs

For the treatment of respiratory infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, *Haemophilus spp.*, *Salmonella spp.*, and *Pasteurella spp.*

For the treatment of urogenital infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, *Escherichia coli*, and *Haemophilus spp.*

For the treatment of skin infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Pasteurella spp.*, *Peptococcus spp.*, and *Peptostreptococcus spp.*

For the treatment of localised soft tissue infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Peptococcus spp.*, and *Peptostreptococcus spp.*

For the treatment of gastrointestinal infections caused by *Escherichia coli*, *Salmonella spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Peptococcus spp.*, and *Peptostreptococcus spp.*

Cats

For the treatment of respiratory infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, *Haemophilus spp.*, *Moraxella spp.*, *Salmonella spp.*, and *Pasteurella spp.*

For the treatment of urogenital infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, and *Escherichia coli*.

For the treatment of skin infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Pasteurella spp.*, *Peptococcus spp.*, and *Peptostreptococcus spp.*

For the treatment of localised soft tissue infections caused by *Staphylococcus spp.*, *Streptococcus spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Peptococcus spp.*, and *Peptostreptococcus spp.*

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.

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.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product is not suited for intravenous or intrathecal injection.

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. Care should be taken to avoid accidental injection and contact with the skin. 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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Allergic reactions
Undetermined frequency (cannot be estimated from the available data):	- Localised tissue reaction -

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:

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

Concurrent use of cephalosporins with potentially nephrotoxic substances (e.g. aminoglycosides, polymyxin antibiotics) or diuretic substances (e.g. furosemide) may increase possible 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 1ml of the product per 25kg 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.

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.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

Administration of Cefalexin at up to twice the recommended dose in cattle and at up to three times the recommended dose in dogs and cats does not produce any adverse effects.

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.

The following micro-organisms have been shown to be sensitive to cefalexin *in vitro*: *Corynebacterium spp.*, *Micrococcus spp.*, *Staphylococcus spp.* (including penicillin-resistant strains), *Streptococcus spp.*, *Actinobacillus lignieresii*, *Escherichia coli*, *Haemophilus spp.*, *Moraxella spp.*, *Salmonella spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Pasteurella spp.*, *Peptococcus spp.*, *Peptostreptococcus spp.*, *Actinomyces bovis*, and *Erysipelothrix rhusiopathiae*.

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* SCC*mec*), 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 tubules. 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 broaching the vial: 28 days.

5.3 Special precautions for storage

Do not store above 25°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

Vm 34534/5015

8. DATE OF FIRST AUTHORISATION

29 October 2025

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 17 December 2025