SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceporex 180 mg/ml Suspension for Injection for Cattle, Cats and Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Cefalexin 180 mg
(equivalent to 191.3 mg cefalexin sodium)

Excipients:

Qualitative composition of excipients and other constituents
Caster oil, hydrogenated
Triglycerides, medium chain

A white to off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, cats and dogs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for antibiotic therapy in cattle, cats and dogs. Cefalexin is a broad spectrum cefalosporin antibiotic with bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria.

The following micro-organisms have been shown to be sensitive to cefalexin *in vitro:*

Staphylococcus spp. (including penicillin-resistant strains)
Streptococcus spp.
Corynebacterium spp.
Pasteurella spp.
Escherichia coli
Proteus spp.
Micrococcus spp.
Moraxella spp.
Actinobacillus lignieresi
Actinomyces bovis
Haemophilus spp.
Erysipelothrix rhusiopathiae
Clostridium spp.
Salmonella spp.
Fusobacterium spp.
Peptostreptococcus spp.
Peptococcus spp.

When susceptible organisms are present, the veterinary medicinal product is indicated in the treatment of infections of the respiratory tract, urogenital tract, the skin and localised infections in soft tissues in dogs and cats. In dogs it may also be effective in the treatment of infections of the gastrointestinal tract.
Trials have shown the product to be of particular value in treating metritis, foot infections, wounds and abscesses and in the treatment of septicaemic mastitis to supplement intramammary therapy in cattle.

3.3 Contraindications

Do not use in cases of hypersensitivity to cefalexin.

3.4 Special warnings

As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not suitable for intravenous or intrathecal administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Cephalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross sensitivity 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 work with such preparations.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
Wash hands after use.
If you develop symptoms following exposure such as a 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.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

3.6 Adverse events

Cattle, cats and dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction; Injection site 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

None.

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. Also see section 3.4.

3.9 Administration routes and dosage

Before withdrawal of a dose the vial should be shaken to resuspend the contents.

This veterinary medicinal product does not contain an antimicrobial preservative. Use a dry needle and syringe. Swab the septum before removing each dose.
To ensure a correct dosage, body weight should be determined as accurately as possible.

Cats and dogs: Subcutaneous use or intramuscular use.
The recommended dose is 10 mg/kg once daily for up to 5 days. Any variation should be at the prescribing veterinary surgeon's discretion, e.g. in severe or acute conditions. After administration massage the injection site.

The following is intended as a guide:

	Weight	**Dose volume**
Cats: up to	4.5 kg	0.25 ml
Dogs: small	5-9.0 kg	0.25-0.5 ml
medium	9.0-27.0 kg	0.5-1.5 ml
large	27.0-54.0 kg	1.5-3.0 ml

Cattle: Intramuscular use.
The recommended dose for cattle is 7 mg/kg (1 ml/25 kg) once daily for up to 5 days.

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: 19 days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DB01.

4.2 Pharmacodynamics

Cefalexin is a semi-synthetic bactericidal antibiotic belonging to the cefalosporin group which acts by interference with bacterial cell wall formation.

Cefalexin is resistant to the action of staphylococcal penicillinase and is therefore active against the strains of *Staphylococcus aureus* that are insensitive to penicillin (or related antibiotics such as ampicillin or amoxycillin) because of production of penicillinase.

Cefalexin is also active against the majority of ampicillin-resistant *E. coli.*

4.3 Pharmacokinetics

Cefalexin is rapidly absorbed after injection. Peak blood concentrations are generally achieved within one hour of administration. Cefalexin is excreted in the urine in high concentration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the presence of water, hydrolysis of cefalexin occurs. It is important, therefore, that a dry syringe is used when extracting suspension for injection to avoid contaminating the remaining contents of the vial with drops of water.

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.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless, multidose 100 ml Type I or Type II glass vial, sealed with a bromobutyl rubber closure and an aluminium cap with tear-off lid.

Pack size:
Cardboard box containing 1 x 100 ml vial.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4127

8. DATE OF FIRST AUTHORISATION

23 December 1992

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

September 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: 22 October 2025