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 substances:
Cefalexin sodium
equivalent to cefalexin 180 mg.

Excipients:

Qualitative composition of excipients and other constituents
Castor oil, hydrogenated
Fractionated Coconut oil

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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. Do not use in cases of known renal insufficiency.

The veterinary medicinal product is not suitable for intravenous or intrathecal or intramammary 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.
If you develop symptoms following exposure such as a skin rash you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

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

3.6 Adverse events

Cattle, cats, dogs:

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

The safety of the veterinary medicinal product has not been established during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Dogs and cats: Subcutaneous or intramuscular use.
Cattle: Intramuscular use.

Before withdrawal of a dose the vial should be shaken to re-suspend 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.

Dogs and cats:
The recommended dose is 10 mg/kg once daily for up to 5 days.

The following is intended as a guide:

Animal	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

After administration massage the injection site.

Cattle:
The recommended dose is 7 mg/kg once daily for up to 5 days.

Species	Dose rate	Dose volume
Cattle	7 mg/kg	1 ml/25 kg

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

Administration of the veterinary medicinal product 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: 15 days.
Milk: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01DB01

4.2 Pharmacodynamics

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.
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 with 1 x 100 ml glass vial.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/223/001

8. DATE OF FIRST AUTHORISATION

01/10/1998

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

16/12/2025

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).