SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active constituents:	mg/ml
Cefalexin sodium equivalent to Cefalexin	180

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection
A white to cream coloured mobile suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, cats and dogs.

4.2 Indications for use

The 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.	*Actinomyces bovis*
Corynebacterium spp.	*Haemophilus* spp.
Pasteurella spp.	*Erysipelothrix rhusiopathiae*
Escherichia coli	*Clostridium* spp.
Proteus spp.	*Salmonella* spp.
Micrococcus spp.	*Fusobacterium* spp.
Moraxella spp.	*Peptostreptococcus* spp.
Actinobacillus lignieresi	*Peptococcus* spp.

When susceptible organisms are present, the 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.

4.3 Contra-indications

Hypersensitivity to cefalexin is very rare, however, it should not be administered to animals which are known to be hypersensitive.

4.4 Special warnings for each 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. In cases of known renal insufficiency the dose should be reduced.

4.5 Special precautions for use

i. Special precautions for use in animals

Not suitable for intravenous or intrathecal administration.

ii. Special Safety Precautions to be taken by the Person Administering the Product

Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure, taking all recommended precautions. Wash hands after use.

3. 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.

4.6 Adverse reactions (frequency and seriousness)

Use of the product may result in localised tissue reaction.
Allergic reactions across all target species have been reported very rarely in spontaneous reports.

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).

4.7 Use during pregnancy, lactation or lay

None.

4.8 Interactions with other medicaments and other forms of interactions

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 4.4.

4.9 Amounts to be administered and administration route

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

This 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. Any variation should be at the prescribing veterinary surgeons discretion, e.g. in severe or acute conditions. 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

The product may be administered by either the subcutaneous or intramuscular route. After administration massage the injection site.

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

The product should be administered by the intramuscular route.

4.10 Overdose

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.

4.11 Withdrawal period(s)

Cattle - 19 days
Cattle (milk) – Zero hours
Animals for human consumption must not be slaughtered during treatment.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QJ01DB01

5.1 Pharmacodynamic properties

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.*

5.2 Pharmacokinetic Properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caster Oil, hydrogenated
Triglycerides, medium chain

6.2 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.

6.3 Shelf life

Shelf life of the veterinary product as packaged for sale 3 years.
Shelf life following withdrawal of the first dose, 28 days

6.4 Special precautions for storage

Do not store above 30°C. Protect from light.
Following withdrawal of the first dose, use the product within 28 days.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused medicinal product or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4127

9. DATE OF FIRST AUTHORISATION

23 December 1992

10. DATE OF REVISION OF THE TEXT

January 2025

Gavin Hall
Approved: 03 January 2025