Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceporex 18 %w/v Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Cefalexin sodium
equivalent to cefalexin 18.0 % w/v
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, cats and dogs.

4.2 Indications for use, specifying the target species

Ceporex Injection 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, Ceporex Injection 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.

4.3 Contraindications

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

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. Do not use in cases of known renal insufficiency.

4.5 Special precautions for use

i) Special precautions for use in animals

Ceporex Injection is not suitable for intravenous or intrathecal or intramammary administration.

ii) Special precautions to be taken by the person administering the 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.

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.

3. If you develop symptoms following exposure such as a skin rash you should seek medial 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.

4.7 Use during pregnancy, lactation or lay

The reproductive safety of Ceporex Injection has not been specifically investigated in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None described.

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. 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

Ceporex Injection 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 once daily for up to 5 days.

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

Ceporex Injection should be administered by the intramuscular route.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Administration of Ceporex Injection 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:
Milk: zero days.
Meat and offal: 15 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QJ01DB01

5.1 Pharmacodynamic properties

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

Hydrogenated castor oil
Fractionated Coconut oil

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

6.4 Special precautions for storage

Do not store above 30^{o}C.
Protect from light.

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 veterinary medicinal products 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 Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/223/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2008

10 DATE OF REVISION OF THE TEXT

January 2012