Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvasol Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Cefalexin 180 mg
(as cefalexin sodium)

Base to 1 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.
An off-white to cream oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Dogs

4.2 Indications for use, specifying the target species

For the treatment of infections caused by, or associated with organisms sensitive to cefalexin in cattle and dogs.
When susceptible organisms are present, Solvasol Injection is indicated in the treatment of infections of the respiratory tract, urogenital tract, the skin and localised infections in soft tissues in dogs. In dogs it may also be effective in the treatment of infections of the gastrointestinal tract.

4.3 Contraindications

Do not use in known cases of hypersensitivity to cephalosporins.

Do not inject intravenously or intrathecally.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Accumulation may occur when renal function is impaired. Use with caution in cases of known renal insufficiency.

Special Precautions to be taken by the Person Administering the 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.

Handle this 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 doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Localised tissue reaction may occur at the injection site.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and mice have not produced evidence of a teratogenic, foetotoxic or maternotoxic effect except at very high doses. No information is available regarding the target species: use only according to the risk/benefit assessment by the responsible veterinarian.
Cefalexin has not been detected in bovine milk following administration of Solvasol Injection.

4.8 Interaction with other medicinal products and other forms of interactions

No data available.

4.9 Amounts to be administered and administration route

Solvasol Injection is indicated for intramuscular or subcutaneous administration to dogs and for intramuscular administration to cattle.

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

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.

Dogs: The recommended dose rate is 10 mg cefalexin/kg bodyweight once daily for up to 5 days.

Cattle: The recommended dose rate is 7 mg cefalexin/kg bodyweight once daily for up to 5 days.Maximum per injection site is 20 ml. Doses greater than 20 ml should be divided between two sites.

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

Studies in cattle and dogs at twice the recommended dose have shown no evidence of adverse effects, other than mild injection site reactions.

4.11 Withdrawal period(s)

Foodstuffs must not be taken for human consumption during the treatment period.

Cattle:
Edible tissues: 6 days
Milk: zero milkings.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Cefalexin is a broad spectrum cephalosporin antibiotic and its structure contains the beta-lactam ring and dihydrothiazine ring common to all cephalosporins.

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

Cephalosporin antibiotics exert their bactericidal effect by preventing the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. The beta-lactam ring of the cephalosporins binds and inhibits the transpeptidase enzymes which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall.
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

Caprilic carprate triglyceride

6.2 Major incompatibilities

In the presence of water, hydrolysis of cefalexin occurs.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Solvasol Injection will be supplied in clear type I multidose vials of 50 ml or 100 ml with nitryl rubber bungs and aluminium caps.
Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/060/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 June 2002
Date of last renewal: 13 June 2007

10 DATE OF REVISION OF THE TEXT

January 2019