Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Depocillin 300 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substances
Procaine benzylpenicillin 300 mg

Excipients
Methyl parahydroxybenzoate (E218) 1.1 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

White to off-white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep, pigs, horses, dogs and cats.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by bacteria sensitive to penicillin.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters or gerbils.
Do not use intravenously.

4.4 Special warnings for each target species

The product will not be effective against beta lactamase producing organisms.

4.5 Special precautions for use

Special precautions for use in animals
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances are occasionally 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 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.

In case of accidental contact with eyes, rinse immediately with copious amounts of water.
Accidental spillage on the skin should be washed off immediately with soap and water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Allergies to penicillin have been observed but these are very rare.
Potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed.
In sucking and fattening pigs, administration of products containing procaine penicillin may cause transient pyrexia, vomiting shivering, listlessness and incoordination.
In pregnant sows and gilts, a vulval discharge which could be associated with abortion has been reported.
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

4.8 Interaction with other medicinal products and other forms of interaction

Depocillin is bacteriocidal. Avoid concurrent use of bacteriocidal and bacteriostatic antibiotics.
There is cross-resistance between penicillins and other beta-lactam antibiotics.

4.9 Amounts to be administered and administration route

Dose: Large animals – 12 mg/kg (1 ml per 25 kg body weight);
Small animals – 30 mg/kg (1 ml per 10 kg body weight).

Suggested doses are:
Cattle 500 kg: 20 ml
Sheep 50 kg: 2 ml
Pigs 50 kg: 2 ml
Horse 500 kg: 20 ml
Dogs 10 kg: 1 ml
Cats 5 kg: 0.5 ml

Routes of administration: Large animals – deep intramuscular injection.
Small animals – intramuscular or subcutaneous injection.

Treatment may be repeated at 24 hour intervals for up to 5 administrations.
Do not use the same injection site more than once during a course of treatment.

Shake well before use.
Clean the area of the injection site and swab with spirit.

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

Penicillin is a compound with a very high therapeutic index. It is unlikely that an overdose will result in any effect other than those mentioned in section 4.6.

4.11 Withdrawal Period(s)

Cattle:
Meat and offal: 6 days.
Milk: 7 days (14 milkings) from the last treatment.

Sheep:
Meat and offal: 4 days.
Milk: Not authorised for use in ewes producing milk for human consumption.

Pigs:
Meat and offal: 5 days.

Horses:
Meat and offal: 6 months.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives for systemic use; Beta-lactam antibacterials, Penicillins, Beta-lactamase sensitive penicillins.
ATCvet code: QJ01CE09

5.1 Pharmacodynamic properties

Penicillin is a beta-lactam antibiotic which has bactericidal activity against mainly Gram-positive bacteria and some Gram-negative aerobes. It is sensitive to beta-lactamase (penicillinase) inactivation.

5.2 Pharmacokinetic properties

Penicillin is widely distributed in the extracellular fluids after absorption, and eliminated almost entirely by the kidneys.
Procaine penicillin gives high initial blood levels; treatment may be repeated at 24 or 48 hour intervals to maintain therapeutic levels.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Lecithin (soya)
Povidone (K30)
Sodium citrate dihydrate
Potassium acid phosphate
Disodium edetate dihydrate
Water for injections
Sodium hydroxide solution (for pH adjustment)
Phosphoric acid solution (for pH adjustment)

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Clear type II glass or PET multidose vials with halogenated butyl rubber stoppers and aluminium closures.
Pack size: 100 ml.

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 product 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 10996/068/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1987
Date of last renewal: 1st October 2007

10 DATE OF REVISION OF THE TEXT

November 2016