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Depocillin® 300 mg/ml suspension for injection

Species: Cats, Dogs, Horses and other equidae, Pigs, Sheep

Therapeutic indication: Pharmaceuticals: Antimicrobials: Injections

Active ingredient: Procaine Benzylpenicillin

Product: Depocillin® 300 mg/ml suspension for injection

Product index: Depocillin®

Cattle - milk: 264 hours

Cattle - meat: 5 days

Sheep - meat: 5 days

Pig - meat: 5 days

Incorporating:

Qualitative and quantitative composition

Each ml contains:

Active substances:

Procaine benzylpenicillin 300 mg

Excipients:

Methyl parahydroxybenzoate 1.10 mg

For the full list of excipients, see section “Pharmaceutical particulars”.

Pharmaceutical form

White to off-white suspension.

Clinical particulars

Target Species

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

Indications for use

The veterinary medicinal product is indicated for the treatment of infections caused by bacteria sensitive to penicillin.

Contraindications

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

Do not use in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other small herbivores.

Not effective against beta-lactamase producing organisms.

Special warnings for each target species

Occasionally in sucking and fattening pigs, administration of products containing procaine penicillin may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination. Additionally in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious.

Furthermore, benzylpenicillin penetrates mammalian cells poorly and hence this product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:

- *Glaesserella parasuis*, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs;
- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica* (only in some member states), as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle;
- *S. aureus*, coagulase negative *Staphylococci* and *Enterococcus* spp. in dogs;
- *Staphylococcus aureus* and *Staphylococcus felis* in cats.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

Special precautions for use

Not recommended for intravenous or intrathecal administration

Operator warnings

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 with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Adverse Reactions

Cattle, horses, sheep, dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports): Hypersensitivity reaction, Anaphyl (e.g., swelling, pain)

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports): Hypersensitivity reactions
Vomiting; Injectic

1 May be life-threatening. Potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed. If such reactions occur appropriate treatment is recommended.

2 In sucking and fattening pigs.

Systemic toxic effects have been observed in young piglets, which are transient but can be potentially lethal, especially at higher doses.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy or lactation

No special precautions necessary

Interactions

Antagonism between the product and bacteriostatic preparations may occur.

Resistant bacteria, particularly gram-negative, that show a cross-resistance with other beta-lactam antibiotics might occur.

Amounts to be administered and administration route

Horses and cattle 12 mg/kg bodyweight, sheep and pigs 15 mg/kg. Intramuscular use.

Dogs and cats 30 mg/kg (1 ml per 10 kg bodyweight). Subcutaneous use.

Suggested doses are:

Cattle	500 kg	20
Horses	500 kg	20
Sheep	50 kg	2.5
Pigs	50 kg	2.5
Dogs	10 kg	1 n
Cats	5 kg	0.5

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

The treatment duration is 3 to 7 days and should be repeated at 24 hour intervals.

Do not use the same injection site more than once during a course of treatment.

Do not inject more than 20 ml per injection site in cattle.

Do not inject more than 5 ml per injection site in pigs and sheep.

Overdose

Penicillin is a compound with a very high therapeutic ratio. It is very unlikely that an overdose of the product will have adverse effects on the treated animal.

Withdrawal periods

Meat and offal:

Cattle, pigs, sheep:

5 days for the treatment duration 3-5 days

7 days for the treatment duration 6-7 days

Horses: Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

Milk:

Cattle: 264 hours (11 days)

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Sheep, horses: Not authorised for use in animals producing milk for human consumption.

Pharmacological particulars

ATCvet code: QJ0ICE09

Pharmacokinetic particulars

fluids after absorption, and eliminated almost entirely by the kidneys.

The procaine penicillin gives high initial blood levels; treatment may be repeated at 24 or 48 hour intervals to maintain therapeutic levels.

Enterobacteriales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas* spp. as well as beta-lactamase-producing *Staphylococcus* spp. are resistant.

Pharmaceutical particulars

Excipients

Methyl parahydroxybenzoate

Lecithin (soya)

Povidone (K30)

Sodium Citrate dihydrate

Potassium Acid Phosphate

Disodium Eddetate Dihydrate

Sodium hydroxide 32% (for pH adjustment)

Phosphoric acid 85% (for pH adjustment)

Water for injections

Major incompatibilities

None known.

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.

Special precautions for storage

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

Keep the vial in the outer carton in order to protect from light.

Immediate packaging

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Multidose vials of neutral Type II glass or PET closed with halogenated butyl rubber stoppers and aluminium closures, containing 100 ml.

Disposal

Medicines should not be disposed of via wastewater.

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.

Marketing Authorisation Holder (if different from distributor)

Intervet International B.V., represented by MSD Animal Health UK Limited.

Marketing Authorisation Number

UK: Vm 06376/4081

Significant changes

Date of the first authorisation or date of renewal

25 September 1996

Date of revision of the text

May 2025.

Any other information

For animal treatment only. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description:Depocillin 1x100ml:

GTIN:8713184011053