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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate	1.10 mg
Lecithin (soya)	
Povidone (K30)	
Sodium citrate dihydrate	
Potassium acid phosphate	
Disodium edetate dihydrate	
Sodium hydroxide 32% (for pH adjustment)	
Phosphoric acid 85% (for pH adjustment)	
Water for injections	

White to off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, sheep, pigs, dogs, cats

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not recommended for intravenous or intrathecal administration.

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

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, horses, sheep, dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction, Anaphylaxis[1]; Injection site reaction (e.g.,swelling, pain)

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction, Anaphylaxis[1]; Vomiting[2]; Injection site reaction (e.g. swelling, pain)

[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.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
No special precautions necessary.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

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

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.

The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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)
Sheep, horses: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CE09

4.2 Pharmacodynamics

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. It is widely distributed in the extracellular 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.
Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas* spp. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 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.

5.4 Nature and composition of immediate packaging

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

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

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4081

8. DATE OF FIRST AUTHORISATION

25 September 1996

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 26 May 2026