1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depocillin 300 mg/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
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 (E218)	1.1 mg
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)	

White to off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

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

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:

- *Glaeserella 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:
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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, sheep, horses, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[1]

[1] Potentially fatal reactions in horses have been observed.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction Pyrexia[1], listless[1;] Vomiting[1] Shivering[1], incoordination[1] Vaginal discharge[2], abortion[2]

[1] In sucking and fattening pigs, transient.
[2] In pregnant sows and gilts.

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

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product is bacteriocidal. Avoid concurrent use of bacteriocidal and bacteriostatic antibiotics.
There is cross-resistance between penicillins and other beta-lactam antibiotics.

3.9 Administration routes and dosage

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

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
Horses 500 kg:	20 ml
Dogs 10 kg:	1 ml
Cats 5 kg:	0.5 ml

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

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

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

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 3.6.

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

Cattle:
Meat and offal: 6 days for treatment duration of 3-5 days.
8 days for a treatment duration of 6-7 days.
Milk: 7 days (14 milkings) from the last treatment.

Sheep:
Meat and offal: 4 days for treatment duration of 3-5 days.
6 days for a treatment duration of 6-7 days.
Milk: Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 5 days for treatment duration of 3-5 days.
7 days for treatment duration of 6-7 days.

Horses:
Meat and offal: 6 months for treatment duration of 3-5 days.
6 months and 2 days for treatment duration of 6-7 days.

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

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

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 Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/068/001

8. DATE OF FIRST AUTHORISATION

01/10/1987

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

19/07/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).