1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procillin 300mg/ml Suspension for Injection for Cattle Sheep and Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance
Procaine Benzylpenicillin 300 mg

Excipients
Methyl Parahydroxybenzoate E218 2.0mg
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
An off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

For the treatment of bacterial infections sensitive to penicillin. These include both gram positive and gram-negative organisms as follows:
Streptococcus spp.
Listeria spp.
Leptospira spp.
Trueperella pyogenes
Bacillus anthracis
Erysipelothrix rhusiopathiae
Corynebacterium pseudotuberculosis
Corynebacterium renale

4.3 Contraindications

Do not inject intravenously.
Do not administered to animals known to be sensitive to penicillin
Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

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:
- *Streptococcus* spp. in pigs.
- *Trueperella pyogenes* in cattle;

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

Pigs: Occasionally in suckling and fattening pigs, administration of 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. Care should be taken not to overdose.
Cattle and Sheep: None.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins and cephalosporins may cause sensitization following injection, inhalation, ingestion or skin contact. Sensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know that you are sensitized, or if you have been advised not to work with such preparations.
Handle this product with care to avoid exposure.
If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips, eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional allergies to penicillin have been observed but these are very rare.
Occasionally in suckling and fattening pigs, administration of such products may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination.
Systemic toxic effects have been observed in young piglets, which are transient but can be potentially lethal, especially at higher doses.

4.7 Use during pregnancy, lactation or lay

Although the use of penicillin has been associated with vulval discharge in pregnant sows and gilts, there is no evidence from the extensive use of Procillin Injection that this product presents any particular hazard to the dam or foetus. Procillin Injection may therefore be used safely in pregnant sows and gilts.

Administration of Procillin Injection to lactating animals may lead to the excretion of antibiotics in milk. Milk from treated animals should be withheld from human consumption in accordance with the instructions at 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

Procillin Injection does not interact with any of the other drugs commonly administered to cattle, sheep or pigs.

4.9 Amounts to be administered and administration route

Administration by intramuscular injection only.
Dosage: 2 ml per 50 kg (equivalent to 12 mg procaine benzylpenicillin per kg) per day.
The treatment duration is 3 to 7 days.
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.
Not more than 20 ml to be injected at any one site.
The vials can only be broached a maximum of 30 times.

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

Care should be taken not to overdose.
Overdosing may invalidate the stated meat and milk withholding times.
Tolerance studies have been conducted at twice the recommended dosage rate in all three target species without any ill-effects being observed.

4.11 Withdrawal period(s)

Cattle
Meat: 10 days for treatment duration 3 days.
12 days for treatment duration 4-7 days.
Milk: 108 hours (9 milkings)
Pigs
Meat: 7 days for treatment duration 3 days.
9 days for treatment duration 4-7 days.
Sheep
Meat: 4 days for treatment duration 3 days.
6 days for treatment duration 4-7 days.
Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Beta-lactamase sensitive penicillins
ATCvet Code: QJ01CE09

5.1 Pharmacodynamic properties

Procillin Injection contains procaine benzylpenicillin, a complex, sparingly soluble organic salt of benzylpenicillin. Use of the procaine salt is intended to delay absorption of the drug from the injection site and to give rise to a longer duration of action than would be expected from benzylpenicillin. In other respects, however, procaine benzylpenicillin shares the properties of benzylpenicillin. Penicillins act by interfering with microbial cell wall synthesis. The spectrum of activity of Procillin Injection is that of benzylpenicillin, which is a narrow spectrum antibiotic with activity mainly against gram-positive organisms. Penicillins are bacteriostatic at low concentrations but bactericidal at higher concentrations.

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

5.2 Pharmacokinetic particulars

Following intramuscular injection of Procillin Injection, peak concentrations of penicillin in plasma are reached within 1 to 2 hours and in all three species plasma levels well exceeded MIC levels for more sensitive organisms at half the recommended inter-dose interval.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Methyl Parahydroxybenzoate (E218)
Sodium Citrate
Disodium Edetate
Lecithin
Potassium dihydrogen phosphate
Potassium chloride
Water for Injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Store in a refrigerator (2°C - 8°C).
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

A clear, Type I glass vial (100ml) and clear, Type III glass vial (250ml) sealed with a bromobutyl rubber stopper and aluminium overseal, containing a sterile aqueous suspension.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
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8. MARKETING AUTHORISATION NUMBER(S)

VPA 22033/043/091

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 October 1987

10 DATE OF REVISION OF THE TEXT

27 May 2024