Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Procillin 300 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Procaine benzylpenicillin	300 mg

Excipients

Methyl parahydroxybenzoate E218 (as preservative)	10 mg

For a 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.
Actinomyces pyogenes
Bacillus anthracis
Erysipelothrix rhusiopathiae
Corynebacterium pseudotuberculosis
Corynebacterium renale

4.3 Contraindications

Do not inject intravenously.
Do not administer 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

Cattle and sheep: None.
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.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the 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 skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips, eyes, or difficulty 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.

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 interactions

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: 2ml per 50kg (equivalent to 12mg procaine benzylpenicillin pr kg). This dose may be repeated at 24 hour intervals over the next two days.
Not more than 20 ml to be injected at any one site.

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
Milk: 108 hours (9 milkings)

Pigs
Meat: 7 days
Sheep
Meat: 4 days
Do not use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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.

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
Water for injection

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

Do not store above 25ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

A clear Type I or Type II glass vial (100 ml), sealed with a bromobutyl rubber stopper, and aluminum overseal, containing a sterile aqueous suspension.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1987
Date of last renewal: 30 September 2007

10 DATE OF REVISION OF THE TEXT

June 2019