Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Pharmacillin 300 mg/ml suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Procaine Benzylpenicillin	300 mg

Excipients:

*Hydroxybenzoate esters	1.5 mg

(*containing Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Methyl Parahydroxybenzoate (E218)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.
White/off-white suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Horses
Cows
Sheep
Pigs.

4.2 Indications for use, specifying the target species

For the treatment of systemic infections caused by or associated with organisms sensitive to penicillin. *In v*itro tests have shown the following organisms to be sensitive.

Corynebacterium pyogenes
Erysipelothrix rhusiopathiae
Listeria spp.
Pasteurella haemolytica
Pasteurella multocida
Staphylococcus spp. (non-penicillinase producing)
Streptococcus spp.

4.3 Contraindications

Do not inject intravenously.
Do not use in known cases of hypersensitivity to penicillins.
Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

Occasionally in suckling and fattening pigs administration of PHARMACILLIN INJECTION may cause a transient pyrexia, vomiting, shivering, listlessness and inco-ordination.

4.5 Special precautions for use

Special precautions for use in animals
Administer by deep intramuscular injection only.

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 sensitivity to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional, potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed.

4.7 Use during pregnancy, lactation or lay

Pharmacillin injection can be safely administered to pregnant and lactating animals. However in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by the intramuscular route after shaking to ensure re-suspension. Normal aseptic precautions should be observed. The recommended dose rate is 10 mg Procaine Penicillin per kg bodyweight, equivalent to 1 ml Pharmacillin per 30 kg bodyweight, daily for 3-5 days.

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

None known.

4.11 Withdrawal Period(s)

Milk for human consumption must not be taken during treatment.
Milk for human consumption may only be taken from cows after 96 hours after the last treatment.

Animals must not be slaughtered for human consumption during treatment.
Cattle, sheep and pigs may be slaughtered only after 5 days from the last treatment.
Horses intended for human consumption must not be slaughtered until 28 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial.
ATCvet Code: QJ01CE09.

5.1 Pharmacodynamic properties

Procaine Penicillin is administered by deep intramuscular injection to create a depot from which benzylpenicillin is slowly liberated. It exerts its effect on multiplying bacteria by interfering with the formation of the cell wall.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Ethyl Parahydroxybenzoate (E214)
Propyl Parahydroxybenzoate (E216)
Povidone K12
Disodium Edetate Dihydrate
Potassium Dihydrogen Phosphate
Sodium Citrate Dihydrate
Polysorbate 80
Lecithin
Simeticone
Water for Injections

6.2 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^{o}C-8 ^{o}C).
Protect from light.

6.5 Nature and composition of immediate packaging

100 ml multidose colourless Type II glass vials with bromobutyl rubber bungs and aluminium seals.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chem-Pharm
Ballyvaughan
Co. Clare
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT