Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Megapen - Strep Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substances	
Procaine Benzylpenicillin	200 mg
Dihydrostreptomycin Sulphate	200 mg
Excipient	
Methyl Parahydroxybenzoate	1.0 mg
Sodium Formaldehyde Sulfoxylate	1.48 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.
A white aqueous solution

4 CLINICAL PARTICULARS

4.1 Target Species

Bovine.

4.2 Indications for use, specifying the target species

For the treatment and control of infections caused by bacteria sensitive to procaine penicillin or dihydrostreptomycin sulphate.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredients.
Do not administer by the intravenous route.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals
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
Avoid direct contact with product. Use gloves when administering the product. Seek medicinal advice if symptoms such as skin rash, swelling of face, lips etc occurs.
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 hypersensitivity and/or anaphylactic reaction may occur.

4.7 Use during pregnancy, lactation or lay

This product may be used in lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration with other antibiotics should be avoided.

4.9 Amounts to be administered and administration route

By intramuscular injection only.
0.5ml to 1ml per 10 kg b.w.
To ensure a correct dosage bodyweight should be determined as accurately as possible.

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

None known.

4.11 Withdrawal Period(s)

Meat: 28 days.
Milk: 72 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01 RA01.
Pharmacotherapeutic group: Antibacterials for systemic use, penicillins, combinations with other antibacterials

5.1 Pharmacodynamic properties

Procaine Penicillin is a broad spectrum antibiotic, active against most gram+ve organisms. It is slowly absorbed after intramuscular injection and has prolonged antibacterial action. Dihydrostreptomycin is active against gram-ve organisms. The combination has synergistic action.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Sodium Formaldehyde Sulfoxylate
Disodium Edetate
Povidone K30
Cetrimide
Sodium Carboxymethylcellulose
Sodium Citrate
Water for Injections

6.2 Incompatibilities

None known.

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 25^{o}C. Protect from light.

6.5 Nature and composition of immediate packaging

100 ml Type II clear glass siliconised vial, sealed with brombutyl stopper and aluminium overseal.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Franklin Pharmaceuticals Ltd.,
Athboy Road,
Trim,
Co. Meath.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10976/008/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

16th November 2009