# Summary of Product Characteristics (SmPC).

## 1. Name of the Medicinal Product

### (a) Product Name: STERIPEN INJECTION

Generic name: Fortified Procaine Benzylpenicillin for Injection

Trade name: NA

### (b) Strength

4.0 Mega IU

### (c) Pharmaceutical Dosage Form

Powder for injection

## 2. Quality and Quantitative Composition

### (a) Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant

Fortified Procaine Penicillin for Injection contains Fortified Procaine Penicillin Sodium 4 mega(3:1).

### (b) Quantitative Declaration The quantity of the active substance must be expressed per dosage unit

Fortified Procaine Penicillin for Injection contains Fortified Procaine Penicillin Sodium 4 mega(3:1).

## 3. Pharmaceutical Form Visual description of the appearance of the product (colour, marking, etc) e.g." Tablet White, circular flat bevelled edge tablets marked "100" on one side

Fortified Procaine Penicillin for Injection is presented as a white, crystalline powder.

## 4. Clinical Particulars

### (a) Therapeutic indications

Fortified Procaine Benzylpenicillin for injection contains 3 parts of Procaine Benzylpenicillin and 1 part of Benzylpenicillin sodium. Benzyl penicillin is highly active against gram-positive cocci and is similar to that of penicillin V in aerobic gram-positive micro-organisms. It is five to ten times more active against gram-negative micro-organisms. Procaine benzylpenicillin is a sustained release drug that is slowly hydrolysed to benzylpenicillin after deep IM injection. Its microbiological properties are the same as those of benzylpenicillin. Fortified Procaine Benzylpenicillin for injection has the same indications as Benzyl penicillin. It is only indicate in mild infections caused by Benzyl penicillin - sensitive bacteria. It is also effective for syphilis, febris hebdomadis, febris recidiva, and gonorrhea.

### (b) Posology and method of administration

It should be limited to use by IM injection. It is prepared by adding requisite amount of water for injection to Fortified Procaine Benzylpenicillin for injection immediately before use. 400000IU to 800000 IU every 12 hours to 24 hours.

**(c) Contraindications**

Allergy to penicillins or procaine is an absolute contra-indication to the use of Fortified Procaine Benzylpenicillin.

**(d) Special warning and precautions for use**

1. Before making a prescription, detailed history of allergy to drugs (food) should be inquired. And skin test for Procaine and benzylpenicillin should be conducted before drug administration.

2. Person who is anaphylaxis to a kind of penicillin may be anaphylaxis to other penicillins or penicillamine.

3. Patients who suffer of asthma, eczema or urticaria should be caution using the product.

4. The product should be prepared just before use.

**(e) Interaction with other medicinal products and other forms of interactions**

Probenecid, aspirin, indometacin, phenylbutazone and sulfanilamide can reduce Procaine benzylpenicillin excreted from kidney tubules, and thus prolong elimination half-life of Procaine benzylpenicilli. Benzylpenicilli can enhance anticoagulation effect of warfare.

**(f) Pregnancy and lactation**

No injury of penicillins was found in animal reproductive test; the safety of the product in the treatment of infection in pregnant women has not been established. So this drug should be used during pregnancy only if the likely benefits of using Procaine benzylpenicillin outweigh the potential risk to the fetus and/or the mother.

A little of Procaine benzylpenicillin is excreted in human milk, caution should be exercised when the product is administered to a nursing woman.

**(g) Effects on ability drive and use machine**

Adverse effects on the ability to drive or operate machinery have not been observed.

**(h) Undesirable effects**

When administered to a hypersensitive patient, anaphylactic shock with collapse and sometimes death may occur within minutes. A generalised sensitivity reaction can occur within 1 to 3 weeks with urticaria, fever, eosinophilia, joint pains, angioneurotic oedema, erythema multiforme and exfoliative dermatitis, although an accelerated urticarial reaction can develop within hours. Glossitis, angular and aphtous stomatitis, and darkening of the tongue are liable to follow the use of penicillin.

**(i) Overdose**

Overdose mainly presented as unwanted effect in central nervous system. Once happened, drug should be withdrawn and measures should be taken. Benzylpenicillin can be eliminated through hemodialysis.

**5. Pharmacological Properties**

**(a) Pharmacodynamic Properties**

Procaine Benzylpenicillin is a combination of benzylpenicillin with the local anesthetic agent procaine. Following deep intramuscular injection, it is slowly absorbed into the circulation and

hydrolyzed to benzylpenicillin—thus it is used where prolonged low concentrations of benzylpenicillin are required.

This combination is aimed at reducing the pain and discomfort associated with a large intramuscular injection of penicillin. It is widely used in veterinary settings.

Specific indications for procaine penicillin include:

- Syphilis
- Respiratory tract infections where compliance with oral treatment is unlikely
- Cellulitis, erysipelas

Procaine penicillin is also used as an adjunct in the treatment of anthrax.

**(b) Pharmacokinetic Properties**

Procaine benzylpenicillin is a sustained release drug that is slowly hydrolysed to benzylpenicillin after deep IM injection. Adults after IM injection of 3MU Procaine benzylpenicillin, Cmax is about 1.6mg/L that is achieved in 2 hours. Trace is still detected after 24 hours. Neonate during the first week of life IM injection of Procaine benzylpenicillin according to 50,000 units per kg weight, average serum concentration is about 7.4～8.8mg/L during 2 to 12 hours, 1.5mg/L at 24 hours. Same dosage given to Neonate over 7 days, the serum concentration is lower, which is 5～6mg/L at 4 hours, 0.4mg/L at 24 hours. 60%~90% of the dose is excreted through kidney.

Benzylpenicillin serum concentrations can be monitored either by traditional microbiological assay or by more modern chromatographic techniques. Such measurements can be useful to avoid central nervous system toxicity in any patient receiving large doses of the drug on a chronic basis, but they are especially relevant to patients with renal failure, who may accumulate the drug due to reduced urinary excretion rates.

**(c) Preclinical safety Data**

Not applicable.

**6. Pharmaceutical Particulars**

**(a) List of excipients**

Not applicable.

**(b) Imcompatibilities**

Not applicable.

**(c) Shelf life**

Three years.

**(d) Special precautions for storage**

Preserve in a sterile, airtight, tamper-proof container, Store at temperature below 25°C.

**(e) Nature and contents of container**

Vials

**7. Marketing Authorization Holder**

**CHUPET PHARM. CO. LTD**

## 8. Marketing Authorization/renewal of the authorization

Attached

## 9. Date of first authorization/renewal of the authorization

May. 2002

## 10. Date of revision of the text

Not applicable.