

Summary of Product Characteristics (SmPC).

1. Name of the Medicinal Product

(a) Product Name

Generic name: FORTIFIED PROCAINE PENICILLIN INJECTION B.P 4 MEGA

(b) Strength

4.0 Mega IU

(c) Pharmaceutical Dosage Form

Powder for injection

2. Quality and Quantitative Composition

Fortified Procaine Penicillin for Injection contains Fortified Procaine Penicillin Sodium 4 mega

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

3. Clinical Particulars

(a) Therapeutic indications

Fortified Procaine Penicillin Injection contains 3 parts of Procaine Penicillin and 1 part of Procaine penicillin sodium. Procaine 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 Penicillin is a sustained releasedrug that is slowly hydrolysed to Procaine penicillin after deep IM injection. Its microbiological properties are the same as those of Procaine penicillin. Fortified Procaine Penicillin Injection has the same indications as Procaine penicillin. It is only indicate in mild infections caused by Procaine penicillin - sensitive bacteria. It is also effective for syphilis, febris hebdomadis, febris recidiva, and gonorrhoea.

(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 Penicillin Injection immediately before use. 400000IU to800000 IU every 12 hours to 24 hours.

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(c) Contraindications

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

(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 Procaine penicillin should be conducted before drug administration.
2. Person who is anaphylaxis to a kind of penicillin may be anaphylaxis to other penicillin 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 Penicillin excreted from kidney tubules, and thus prolong elimination half-life of Procaine Procaine penicillin. Procaine penicillin can enhance anticoagulation effect of warfare.

(f) Pregnancy and lactation

No injury of penicillin 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 Penicillin outweigh the potential risk to the fetus and/or the mother.

A little of Procaine Penicillin 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 aphthous 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. Procaine penicillin can be eliminated through hemodialysis.

5. Pharmacological Properties

(a) Pharmacodynamic Properties

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

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hydrolyzed to Procaine penicillin—thus it is used where prolonged low concentrations of Procaine penicillin 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 Penicillin is a sustained release drug that is slowly hydrolysed to Procaine penicillin after deep IM injection. Adults after IM injection of 3MU Procaine Procaine penicillin, C_{max} 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 Penicillin 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.

Procaine penicillin 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

Sodium Citrate, Sodium Carboxy Methyl cellulose & Citric acid anhydrous.

Incompatibilities

Not applicable.

(b) Shelf life

Three years.

(c) Special precautions for storage

Store in room temperature at 30⁰c

(d) Nature and contents of container

Vials

JECAIN FORTIFIED PROCAINE PENICILLIN INJECTION B.P 4 MEGA

7. MANUFACTURED BY:

REYOUNG PHARMACEUTICAL CO., LTD

No.1, Ruiyang Road, Yiyuan County, Shandong,
China.

5. MARKETED BY:

NASAJONES INDUSTRIES LIMITED

No. 31 Office Complex, Middle Road By Ado
Bayero Square, Sabon Gari, Kano, Kano State,
Nigeria.
