

FORTIFIED PROCAINE PENICILLIN INJECTION 4 MEGA
Fortified Procaine Penicillin for Injection 4mega

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1-Name of the Medicinal Product : Fortified Procaine Penicillin for Injection 4mega

1.1 Product Name: Fortified Procaine Penicillin for Injection

1.2 Strength: 4mega

1.3 Pharmaceutical Dosage Form: powder for injection

2-Quality and Quantitative Composition :

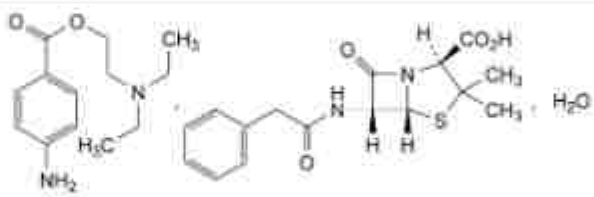
2.1 Qualitative Declaration

The active substance of the Fortified Procaine Penicillin for Injection is Fortified Procaine Penicillin.

Fortified Procaine Penicillin : White or almost white, crystalline powder.

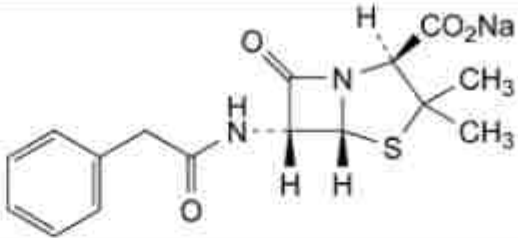
Fortified Procaine Penicillin (API) is a mixture of procaine benzylpenicillin and benzylpenicillin sodium according to the titer ratio of 3:1.

Procaine Benzylpenicillin:

Structural Formula	
Procaine Benzylpenicillin	
Molecular formula	
Procaine Benzylpenicillin	$C_{29}H_{38}N_4O_6S \cdot H_2O$
Molecular weight	
Procaine Benzylpenicillin	588.7

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Benzylpenicillin Sodium:

Structural Formula	
Benzylpenicillin Sodium	
Molecular formula	
Benzylpenicillin Sodium	$C_{16}H_{17}N_2NaO_4S$
Molecular weight	
Benzylpenicillin Sodium	356.4

2.2 Quantitative Declaration

Fortified Procaine Penicillin for Injection 4mega

Dosage form: powder for injection

Concentration: 4mega

Product description: 4mega(3.6g) of white, crystalline powder is filled in the glass vial

Ingredients	Quantity per vial	Function of ingredients
Fortified Procaine Penicillin	4mega(3.6g)	Active substance

3-Pharmaceutical Form :

Dosage form: powder for injection

4mega(3.6g) of white, crystalline powder is filled in the glass vial

4-Clinical Particulars

4.1 Therapeutic indications

Because of its low blood concentration, its application is limited to mild and moderate infections caused by highly sensitive pathogens of penicillin, such as tonsillitis, scarlet fever, erysipelas and pneumococcal pneumonia caused by Group A streptococcus. Penicillin sensitive Staphylococcus aureus caused by furuncle, carbuncle, and perphenazine isthmus, and so on. This product can be used to treat leptospirosis, recurrent fever and early syphilis.

4.2 Posology and method of administration

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The product is used for intramuscular injection. Before application, appropriate amount of sterilization water for injection is added to make the suspension, 400,000 ~ 800,000 units each time, 1-2 times a day.

4.3 Contraindications

Those who have the history of benzylpenicillin allergy or showing positive reaction in benzylpenicillin and procaine skin testing are forbidden.

4.4 Special warnings and precautions for use

- (1) Ask about the history of drug allergy in detail and conduct benzylpenicillin skin test and procaine skin test before using this product.
- (2) People with a benzylpenicillin allergy history may be allergic to other benzylpenicillin drugs and penicillamine.
- (3) Patients with allergic diseases such as asthma, eczema, withered grass fever, urticaria and other allergic diseases should be careful to use this product.
- (4) Application of this product should be freshly prepared.
- (5) During the application of benzylpenicillin, the determination of urine sugar by copper sulfate may be false-positive, but the glucose enzymatic method will not be affected. Most penicillin applications can increase serum alanine aminotransferase or aspartate aminotransferase.

4.5 Interaction with other medicinal products and other forms of interaction

Propanacid, Aspirin, Indomethacin, Protathione and Sulfanilamide reduce renal tubular secretion of benzylpenicillin and prolong the serum half-life of this product. Benzylpenicillin can enhance the anticoagulant effect of warfarin.

4.6 Pregnancy and lactation

The fetal damage caused by benzylpenicillin has not been found in animal reproductive test, but strict control test has not been carried out in pregnant women to eliminate the adverse effects of these drugs on the fetus, so pregnant women still have to weigh the pros and cons. A small amount of this product is secreted from milk and lactating women should stop taking breastfeeding during the medication.

4.7 Effects on ability to drive and use machines

N.A.

4.8 Undesirable effects

- (1) Allergic Reaction: Urticaria and other types of rash are more common,

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leukopenia, interstitial nephritis, asthma attacks and serological disease type reaction is relatively rare; anaphylactic shock occasionally, once occurred, must be

local rescue, to keep the airway smooth, Oxygen inhalation and administration of epinephrine, glucocorticoid and other treatment measures.

(2)Hershey's reaction and treatment contradiction: treatment with procaine penicillin for syphilis, leptospirosis and other diseases can be caused by the death of pathogens to aggravate symptoms, known as the Hershey reaction; treatment conflict also found in syphilis patients, The syphilis focus disappeared too quickly after treatment, but the tissue repair was relatively slow or the fibrous tissue contracted at the lesion site, which obstructed the organ function.

(3)Double infection: penicillin resistant *Staphylococcus aureus*, Gram-negative bacilli or *Candida* double infection.

4.9 Overdose

The main manifestation of drug overdose is the adverse reaction of central nervous system. Hemodialysis clears penicillin.

5-Pharmacological properties

5.1 Pharmacology and toxicology

This product is procaine salt of penicillin and its antibacterial active ingredient is penicillin. Penicillin has good antibacterial activity against streptococcus such as hemolytic streptococcus, streptococcus pneumoniae and staphylococcus without penicillin enzyme. *Neisseria gonorrhoeae*, *neisseria meningitidis*, *corynebacterium diphtheriae*, *bacillus anthracis*, *actinomyces bovis*, streptococcus candida, *listeria listeriae*, leptospira and treponema pallidum are sensitive to this product. It also has antibacterial activity against haemophilus influenzae and bordetella pertussis. This product has good antibacterial effect on the anaerobic bacteria such as clostridium, streptococcus digestis and bacteroides melanoides, but poor antibacterial effect on bacteroides fragilis. Penicillin ACTS as a bactericidal agent by inhibiting the synthesis of bacterial cell walls.

5.2 Pharmacokinetics

After intramuscular injection of Procaine penicillin for injection, benzylpenicillin was slowly released and absorbed. After 300,000 units were injected intramuscularly in adults, the peak concentration in plasma, about 1.6mg/L, would reach in 2 hours and trace can be detected 24 hours later. After intramuscular injection of 50,000 units / kg for newborns who are within 1 week of birth, the mean blood drug concentration was 7.4mg/L to 8.8mg/L, then 1.5mg/L 24 hours later. The same dosage are given to the newborns more than one week old, the plasma concentration is lower, 5mg/l to 6 mg/l 4 hours later and 0.4 mg/l 24 hours

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later. About 60% to 90% of the dose is excreted through the kidney.

5.3 Preclinical safety data

N.A

6-Pharmaceutical Particulars :

6.1 List of excipients

There is no excipients used in the Fortified Procaine Penicillin for Injection manufacturing.

6.2 Incompatibilities

The stability of the drug product demonstrated that there was no compatibility problem between drug substance and packaging materials.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Shading and airtight storage.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

A mode sodium-calcium glass molded injection bottle.

6.6 Special precautions for disposal

N.A

7-Name Of Manufacturer & Marketing Authorization Holder :

7.1 Manufacturer:

Anhui Chengshi Pharmaceutical Co., Ltd.

No. 5068 Huaishang road, Bengbu, Anhui province, China

E-mail: csyy2827111@163.com

7.2 Marketing Authorization Holder:

Fourone Global Resources pharmaceutical Ltd

24 muritala mohammad way posite FCMB BANK ILORIN KWARA STATE

Email: youngpharmareg@gmail.com



163*66*62mm

Size : 125x178mm

GLOBAL YOUNG

FORTIFIED PROCAINE PENICILLIN INJECTION 4MEGA
(Fortified Procaine Penicillin for Injection BP4MEGA)
For IM Injection

This preparation is available in the form of a sterile dry powder containing benzyl penicillin potassium (or sodium) and procaine penicillin with only suspending and buffering agents. The advantage of such a preparation is that it can exert both the prompt action due to the high initial blood levels produced by the soluble potassium salt and the prolonged action of the insoluble procaine penicillin salt which is absorbed and excreted slowly. Therefore a single dose injection of this preparation can maintain an effective concentration in blood for 12-24 hours.

COMPOSITION:

Each vial contains:

Procaine benzylpenicillin BP 3,000,000IU (3g)

Benzylpenicillin sodium BP 1,000,000IU (0.6g)

INDICATION:

It has the same indications as penicillin & used for the treatment of bacterial infections susceptible to penicillin. As its peak blood concentration is relatively low, it is only indicated in mild infections caused by penicillin sensitive bacteria such as tonsillitis, scarlet fever, erysipelas, furuncles and carbuncles. It is also effective for the treatment of syphilis, Vincent's angina and gonorrhea.

ADMINISTRATION AND DOSAGE:

It is given by IM injection only. A suitable amount of water for injection is added into the vial before use. 400,000IU - 800,000IU each time, once or twice a day.

PRECAUTION:

Before administration, skin tests of procaine and penicillin should be made. It should not be administered to patients hypersensitive to penicillin and procaine. The suspension, prepared by adding a suitable amount of water for injection into the vial, should be stored below 15°C and used up within 24 hours.

PRESENTATION

A box of 10 vials.

STORAGE INSTRUCTIONS:

Store in cool and dry place (below 30°C), protect from light. Do not freeze. Reconstituted solution should be stored in original vials.

KEEP OUT OF REACH OF CHILDREN.

MANUFACTURED BY:

Anhui Chengshi Pharmaceutical Co., Ltd.
No. 5068 Huaishang Road, Bengbu, Anhui province, China

MARKETED BY:

Global Young Pharma Limited.
Agara Baba Pupa, Road 5 (House NO.3) Off Odo-Ona Elewe, New Garage, Ibadan Oyo State, Nigeria