



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

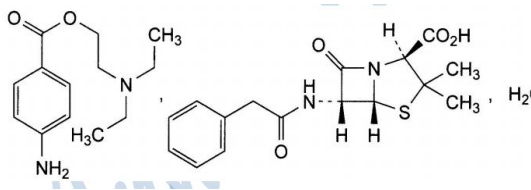
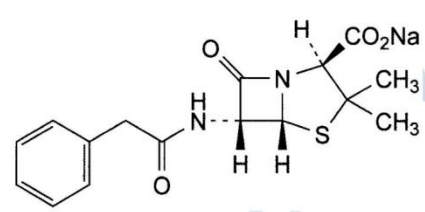
1.2 Strength: 4mega

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 is a mixture of procaine benzylpenicillin and benzylpenicillin sodium according to the titer ratio of 3:1.

	Procaine Benzylpenicillin	Benzylpenicillin Sodium
Physical description	A white or almost white, crystalline powder; odourless or almost odourless	A white crystalline powder
Chemical Abstracts Service (CAS) registry number	54-35-3	69-57-8
Structure		
Molecular formula	$C_{29}H_{38}N_4O_6S \cdot H_2O$	$C_{16}H_{17}N_2NaO_4S$
Molecular weight	588.7	356.4



2.2 Quantitative Declaration

Fortified Procaine Penicillin for Injection 4mega

Dosage form: powder for injection

Concentration: 4mega

Product description: A white, crystalline powder is filled in the sodium calcium glass molded bottle .

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

3-Pharmaceutical Form :

Dosage form: powder for injection

4mega of white, crystalline powder is filled in the clear glass vial .

4-Clinical Particulars

4.1 Therapeutic indications

Fortified Procaine Penicillin for Injection can be used for the treatment of the following cases:

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

4.2 Posology and method of administration

- Recommended doses :

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

4.3 Contraindications

It is contraindicated in patients with a history of allergy to penicillin drugs or procaine, and in patients with positive skin test for penicillin or procaine.

4.4 Special warning and precautions for use

①.Before the application of this product, the patient should be asked about the history of drug allergy and the skin test of penicillin and procaine.



②. People who are allergic to one type of penicillin may be allergic to other penicillins, penicillamine.

③. Patients with asthma, eczema, hay fever, urticaria and other allergic diseases should use this product with caution.

④. The application of this product must be fresh preparation.

⑤. During the application of penicillin, the determination of urine sugar by copper sulfate method may appear false positive, but the use of glucosase method is not affected; Most penicillin treatments increase the level of serum alanine aminotransferase or aspartate aminotransferase.

4.5 Interaction with other medicinal products and other forms of Interactions
Promethacin, aspirin, indomethacin, butazone and sulfonamides reduce the secretion of penicillin in renal tubules and prolong the serum half-life of the product. Penicillin can enhance the anticoagulant effect of warfarin.

4.6 Pregnancy and lactation

Animal reproductive tests have found no harm from penicillin, but strict controlled trials have not been conducted in pregnant women to rule out adverse effects of these drugs on the fetus, so their use in pregnant women must be weighed. A small amount of this product is secreted from milk, lactating women use drugs to stop breastfeeding.

4.7 Child medication

It's not clear.

4.8 Elderly medication

It's not clear.

4.9 Undesirable effects

①. Allergic reactions: urticaria and other types of rashes are more common, leukopenia, interstitial nephritis, asthma attacks and serum disease type reactions are less common; Anaphylactic shock is occasionally seen. Once it occurs, emergency treatment must be carried out on the spot, with airway unblocked, oxygen inhalation, epinephrine, glucocorticoids and other treatment measures.

②. Hector's reaction and treatment contradictions: the use of procaine penicillin in the treatment of syphilis, leptospirosis and other diseases can be due to the death of the pathogen caused by the aggravation of symptoms, known as Hector's reaction; Treatment contradictions are also seen in patients with syphilis, which is caused by the rapid loss of syphilis lesions after treatment and the relatively slow repair of tissue or the contraction of fibrous tissue at the lesion site, which hinders organ function.

③. Double infection: Penicillin-resistant Staphylococcus aureus, Gram-negative bacilli or Candida double infection may occur. 4. Glucocorticoid withdrawal syndrome. Sometimes, after withdrawal of the drug, patients may experience



dizziness, fainting tendencies, abdominal or back pain, low fever, loss of appetite, nausea, vomiting, muscle or joint pain, headache, fatigue, weakness, and upon careful examination, glucocorticoid-dependent syndrome may be considered if adrenal cortical dysfunction and reburning of the original disease can be ruled out.

4.10 Overdose

The main manifestation of drug overdose is the adverse reaction of central nervous system. The drug should be stopped in time and given symptomatic and supportive treatment. Hemodialysis clears penicillin.

4.11 Pharmacology and toxicology

This product is the 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 penicillinase. Neisseria gonorrhoeae, Neisseria meningitidis, Corynebacterium diphtheria, Bacillus anthracis, Actinomyces bovis, Streptobacillus candida, Listeria, Leptospira and Treponema pallidum are sensitive to this product. It also has antibacterial activity against Haemophilus influenzae and Borutella pertussis. This product has good antibacterial effect on aerobes such as Clostridium, Streptococcus digestii and Bacteroides melaninogenes, but poor antibacterial effect on Bacteroides fragility. Penicillin plays a bactericidal role by inhibiting bacterial cell wall synthesis.

4.12 Pharmacokinetics

After intramuscular injection of procaine penicillin, penicillin is slowly released and absorbed. After intramuscular injection of 300 thousand units in adults, the peak plasma concentration (C_{max}) reached about 1.6 mg/L in 2 hours, and could still be measured at a trace level 24 hours later. After intramuscular injection of 50,000 units /Kg of neonatal weight in the first week of birth, the average blood drug concentration was 7.4 ~ 8.8 mg/L at 2 ~ 12 hours and 1.5 mg/L at 24 hours. When the same dose was given to neonates above 1 week old, the plasma concentration was lower, 5 ~ 6 mg/L for 4 hours and 0.4 mg/L for 24 hours. Approximately 60% to 90% of the dose is excreted through the kidney.

5-Pharmaceutical Particulars :

5.1 Shelf life
36 months

5.2 Special precautions for storage
Keep closed and in a dry place.

6-Marketing Authorization Holder :

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

安徽城市药业股份有限公司
Anhui Chengshi Pharmaceutical Co.,Ltd



Anhui Chengshi Pharmaceutical Co.,Ltd
安徽城市药业股份有限公司

7-Name Of Manufacturer :

Anhui Chengshi Pharmaceutical Co.,Ltd.

No.5068.Huashang Road, Bengbu, Anhui Province, China

安徽城市药业股份有限公司
Anhui Chengshi Pharmaceutical Co.,Ltd