



REYOUNG

瑞阳制药股份有限公司

REYOUNG PHARMACEUTICAL CO., LTD.

1.4 Product Information

1.4.1 Prescribing information (Summary of Product Characteristics)

1. Name of the Product

Fortified Procaine Penicillin for Injection 4mega

2. Pharmaceutical Form:

Sterile Powder for Injection

3. Qualitative/Quantitative Composition:

Each vial contains procaine penicillin 3000,000IU and benzylpenicillin sodium 1000,000IU

4. Clinical Particulars

4.1 Therapeutic indications

Moderately severe to severe infections of the upper respiratory tract, skin and soft-tissue infections, scarlet fever, and erysipelas due to susceptible streptococci (Group A-without bacteremia).

Moderately severe infections of the respiratory tract due to susceptible pneumococci.

Fusospirochetosis (Vincent's gingivitis and pharyngitis). Moderately severe infections of the oropharynx due to susceptible fusiform bacilli and spirochetes.

Syphilis (all stages) due to susceptible Treponema pallidum.

Yaws, Bejel, Pinta due to susceptible organisms.

Fortified Procaine Penicillin is an adjunct to antitoxin for prevention of the carrier stage of diphtheria due to susceptible C. diphtheriae.

Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure): to reduce the incidence or progression of the disease following exposure to aerosolized Bacillus anthracis.

4.2 Posology and method of administration

Dosage and administration

It is given by I.M. injection only. A suitable amount of Water for Injection is added into the vial before use. 400,000 I.U.-800,000 I.U. each time, once or twice a day.

4.3 Contraindications

A previous hypersensitivity reaction to any penicillin is a contraindication.

4.4 Special warnings and special precautions for use

Warnings

Fortified Procaine Penicillin should only be prescribed for the indications listed in this insert.

Anaphylaxis serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been



reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of Penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before initiating therapy with any Penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to Penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

Pseudomembranous Colitis

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including Penicillin G, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridium. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.”

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management of fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

Procaine Reactions

Immediate toxic reactions to procaine may occur in some individuals, particularly when a large single dose is administered (4.8 million units). These reactions may be manifested by mental disturbances, including anxiety, confusion, agitation, depression, weakness, seizures, hallucinations, combativeness, and expressed “fear of impending death.” The reactions noted in carefully controlled studies occurred in approximately one in 500 patients who received large doses of Penicillin G Procaine. Reactions are transient, lasting from 15 to 30 minutes.

Method of Administration

Do not inject into or near an artery or nerve.

Injection into or near a nerve may result in permanent neurological damage.



瑞阳制药股份有限公司

REYOUNG

REYOUNG PHARMACEUTICAL CO., LTD.

Inadvertent intravascular administration, including inadvertent direct intra-arterial injection or injection immediately adjacent to arteries, of Penicillin G Procaine Injectable Suspension and other Penicillin preparations has resulted in severe neurovascular damage, including transverse myelitis with permanent paralysis, gangrene requiring amputation of digits and more proximal portions of extremities, and necrosis and sloughing at and surrounding the injection site. Such severe effects have been reported following injections into the buttock, thigh, and deltoid areas. Other serious complications of suspected intravascular administration which have been reported include immediate pallor, mottling, or cyanosis of the extremity, both distal and proximal to the injection site, followed by bleb formation; severe edema requiring anterior or posterior compartment fasciotomy in the lower extremity. The above-described severe effects and complications have most often occurred in infants and small children. Prompt consultation with an appropriate specialist is indicated if any evidence of compromise of the blood supply occurs at, proximal to, or distal to the site of injection.

Quadriceps femoris fibrosis and atrophy have been reported following repeated intramuscular injections of penicillin preparations into the anterolateral thigh.

Caution:

1. Before administration skin tests of Procaine and Penicillin should be made. It should not be administered to patients hypersensitive to Penicillin and Procaine.
2. The suspension prepared by adding a suitable amount of Water for Injection into the vial should be stored below 10°C and used up within 24 hours.

4.5 Interaction with other FPPs and other forms of interaction

Drug Interactions

Tetracycline, a bacteriostatic antibiotic, may antagonize the bactericidal effect of Penicillin and concurrent use of these drugs should be avoided.

Concurrent administration of Penicillin and probenecid increases and prolongs serum Penicillin levels by decreasing the apparent volume of distribution and slowing the rate of excretion by competitively inhibiting renal tubular secretion of Penicillin.

4.6 Pregnancy and lactation

Pregnancy

Teratogenic effects—Pregnancy Category B: Reproduction studies performed in the mouse, rat, and rabbit have revealed no evidence of impaired fertility or harm to the fetus due to penicillin G. Human experience with the penicillins during pregnancy has not shown any positive evidence of



adverse effects on the fetus. There are, however, no adequate and well-controlled studies in pregnant women showing conclusively that harmful effects of these drugs on the fetus can be excluded. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Penicillins are excreted in human milk. Caution should be exercised when penicillins are administered to a nursing woman.

4.7 Effects on ability to drive and use machines

Not reported.

4.8 Undesirable effects

Adverse Reactions

Allergic Reactions

Penicillin is a substance of low toxicity but does possess a significant index of sensitization. The following hypersensitivity reactions associated with use of Penicillin have been reported: Skin rashes, ranging from maculopapular eruptions to exfoliative dermatitis; urticaria; serum-sicknesslike reactions, including chills, fever, edema, arthralgia, and prostration. Severe and often fatal anaphylaxis has been reported. As with other treatments for syphilis, the Jarisch-Herxheimer reaction has been reported.

Procaine toxicity manifestations and hypersensitivity reactions have been reported.

Gastrointestinal

Pseudomembranous colitis has been reported with the use of Penicillin G. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

5. Pharmacological properties

Pharmacology

This preparation is available in the form of a sterile dry powder containing benzylpenicillin Potassium and procaine penicillin with suitable amount of 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.

Action and uses:



Penicillin is a broad spectrum antibiotic with a bacteriocidal property on a wide variety of bacteria that causes wide variety of commonly occurring infections.

Penicillin works by eliminating or inhibiting the growth of bacteria that causes the infections.

Penicillin is used in the treatment of Gram-positive aerobes and anaerobes such as staphylococcus, streptococcus and pneumonia. It is active against gram negative cocci such as gonorrhoea also active against gram negative bacilli such as pseudomonas specie.

Penicillin may be used to treat infections of the upper respiratory tract, skin and soft tissue, dental abscesses and ears infections. It is used in treating and preventing infections with streptococcus bacteria, preventing occurrence of rheumatic fever and pneumococcal infections, tonsillitis, scarlet fever, erysipelas, furuncles and carbuncles. It is also effective for syphilis & Vincent's angina.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Fortified Procaine Penicillin for Injection should not be stored above 30°C. The reconstituted solution should be stored at 2-8°C in a refrigerator and used within 24 hours.

6.5 Nature and contents of container

20ml Type II (soda-lime) glass vial, sealed with Al- cap.

Packs of 5 vials/tray/middle box, 12 middle boxes/carton.

6.6. Instructions for use and handling

The vials of Fortified Procaine Penicillin for Injection are not suitable for multi-dose use. Any residual solution of Fortified Procaine Penicillin Sodium should be discarded

7. Marketing authorisation holder:

Reyoung Pharmaceutical Co., Ltd.

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