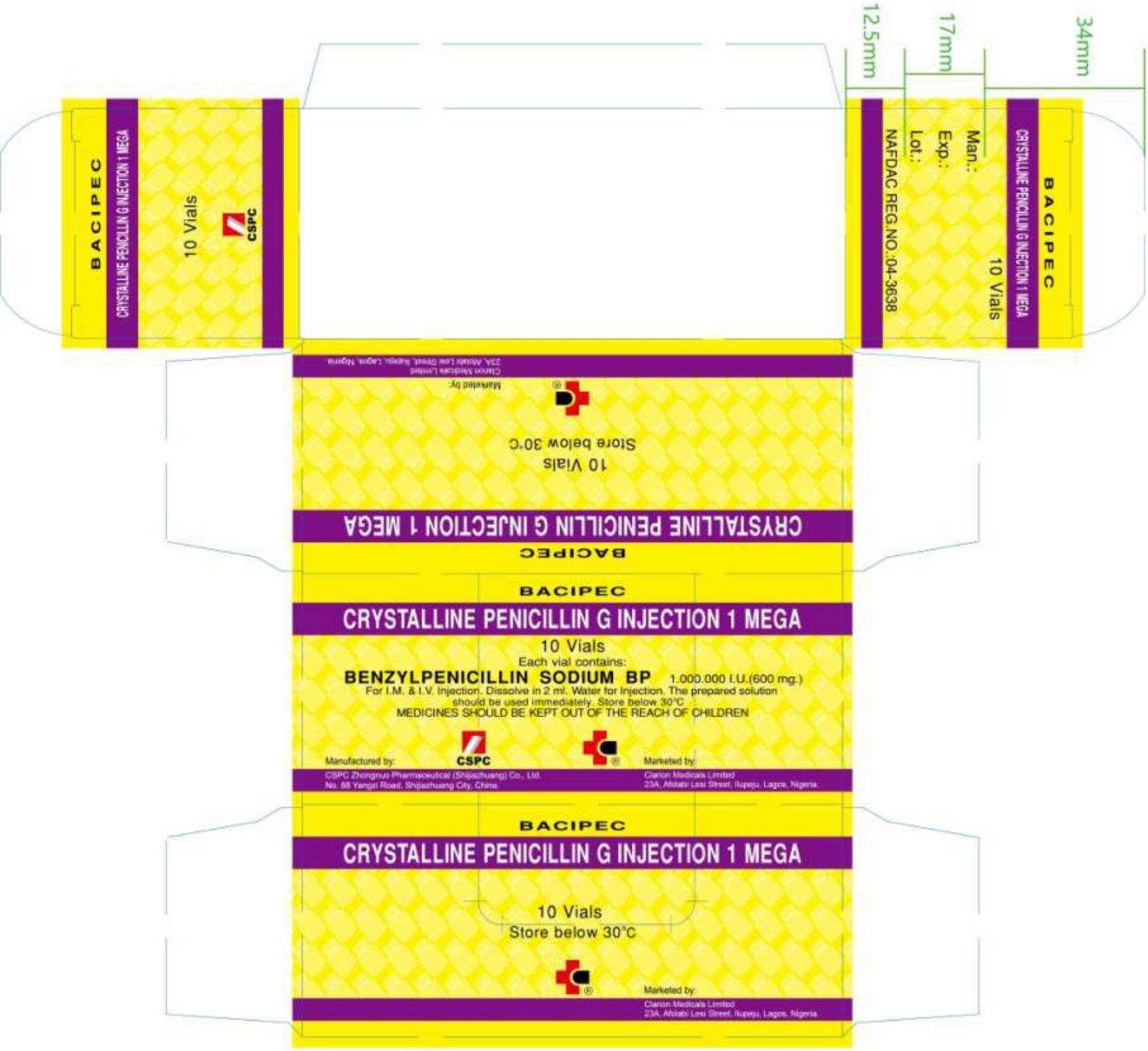
12.5mm
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BACIPEC
CRYSTALLINE PENICILLIN G INJECTION 1 MEGA
10 Vials
CSPC
NAFDAC REG.NO.:04-3638
Lot.:
Exp.:
Man.:
BACIPEC
CRYSTALLINE PENICILLIN G INJECTION 1 MEGA
10 Vials
Store below 30°C
Manufactured by:
Clarion Medicals Limited
23A, Afolabi Lesi Street, Ilupeju, Lagos, Nigeria.
BACIPEC
CRYSTALLINE PENICILLIN G INJECTION 1 MEGA
10 Vials
Each vial contains:
BENZYLPENICILLIN SODIUM BP 1.000.000 I.U.(600 mg.)
For I.M. & I.V. Injection. Dissolve in 2 ml. Water for Injection. The prepared solution should be used immediately. Store below 30°C.
MEDICINES SHOULD BE KEPT OUT OF THE REACH OF CHILDREN
Manufactured by:
CSPC
CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.
No. 88 Yangzi Road, Shijiazhuang City, China.
Marketed by:
Clarion Medicals Limited
23A, Afolabi Lesi Street, Ilupeju, Lagos, Nigeria.
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BACIPEC
CRYSTALLINE PENICILLIN G INJECTION 1 MEGA
Each vial contains:
BENZYLPENICILLIN SODIUM BP

BACIPEC

BENZYL PENICILLIN SODIUM FOR INJECTION B P

DESCRIPTION: Bacipec is a white sterile crystalline powder, which is very soluble in water and has a property of moisture absorption. It rapidly lose its activity toward acids, alkalies or oxidizer, its solution should be stored at low temperature not exceeding 24 degrees.

INDICATION: Aqueous penicillin G (parenteral) is indicated in the therapy of severe infections caused by penicillin G-susceptible microorganisms when rapid and high penicillin levels are required in the conditions listed below. Therapy should be guided by bacteriological studies (including susceptibility tests) and by clinical response.

The following infections will usually respond to adequate dosage of aqueous penicillin G (parenteral):

Streptococcal infections:

Pneumococcal infections.

Staphylococcal infections † penicillin G sensitive.

Anthrax,
Actinomycosis,
Clostridial infections (including tetanus),
Diphtheria (to prevent carrier state),
Erysipeloid (*Erysipelothrix insidiosa*) endocarditis,

Fusospirochetal infections † severe infections of the oropharynx (Vincent's), lower respiratory tract and genital area due to *Fusobacterium fusiformisans spirochetes.*

Gram-negative bacillary infections (bacteremias) † (*E. coli* , *A. aerogenes*, A. faecalis, Salmonella, Shigella and *P. mirabilis*).

Listeria infections (*Listeria monocytogenes*).

Meningitis and endocarditis.

Pasteurella infections (*Pasteurella multocida*).

Bacteremia and meningitis.

Rat-bite fever (Spirillum minus or Streptobacillus moniliformis),

Gonorrheal endocarditis and arthritis (*N. gonorrhoeae*)

Syphilis (*T. pallidum*) including congenital syphilis.

Meningococcic meningitis.

DOSAGE AND ADMINISTRATION

Severe infections due to Susceptible Strains of Streptococci, Pneumococci, and Staphylococci: bacteremia, pneumonia, endocarditis, pericarditis, empyema, meningitis and other severe infections- a minimum of 5 million units daily.

Syphilis: Aqueous penicillin G may be used in the treatment of acquired and congenital syphilis but because of the necessity of frequent dosage, hospitalization is recommended. Dosage and duration of therapy will be determined by age of patient and stage of the disease.

Gonorrheal endocarditis: a minimum of 5 million units daily.

Meningococcic meningitis: 1-2 million units intramuscularly every 2 hours, or continuous IV drip of 20-30 million units/day.

Actmomycosis: 1-6 million units/day for cervicofacial cases, 10-20 million units/day for thoracic and abdominal disease.

Clostridial infections: 20 million units/day penicillin is adjunctive therapy to antitoxin,

Fusospirochetal infections: severe infections of oropharynx, lower respiratory tract, and genital area 5-10 million units/day.

Rat-bite fever (Spirillum minus or Streptobacillus moniliformis): 12-15 million unit/day for 3-4 weeks.

Listeria infections (Listeria monocytogenes):

Neonates- 500,000 to 1 million units/day.
Adults with meningitis- 15-20 million units/day for 2 weeks.
Adults with endocarditis -15-20 million units/day for 4 weeks.

Pasteurella infections (Pasteurella multocida):

Bacteremia and meningitis- 4-6 million units/day for 2 weeks.

Erysipeloid (Erysipelothrix insidiosa) Endocarditis: 2-20 million units/day for 4-6 weeks.

Gram-negative bacillary infections (*E. coli* , *Enterobacter aerogenes*, *A. faecalis*, *Salmonella*, *Shigella and Proteus mirabilis*):

Bacteremia- 20-80 million units/day.

Diphtheria: carrier state- 300,000–400,000 units of penicillin/day in divided doses for 10-12 days.

Anthrax: A minimum of 5 million units of penicillin/day in divided doses until cure is effected.

THE 20,000,000 UNIT DOSAGE MAY BE ADMINISTERED BY INTRAVENOUS INFUSION ONLY.

(1) Intramuscular Injection: Keep total volume of injection small. The intramuscular route is the preferred route of administration. Solutions containing up to 100,000 units of penicillin per mL of dilutent may be used with a minimum of discomfort. Greater concentration of penicillin G per mL is physically possible and may be employed where therapy demands. When large dosages are required, it may be advisable to administer aqueous solutions of penicillin by means of continuous intravenous drip

(2) Continuous Intravenous Drip: Determine the volume of fluid and rate of its administration required by the patient in a 24 hour period in the usual manner for fluid therapy and add the appropriate daily dosage of penicillin to this fluid. For example, if an adult patient requires 2 liters of fluid in 24 hours and a daily dosage of 10 million units of penicillin, add 5 million units to 1 liter and adjust the rate of flow so the liter will be infused in 12 hours.

(3) Intrapleural or Other Local Infusion: If fluid is aspirated, give infusion in a volume equal to ¼ or ⅓ the amount of fluid aspirated, otherwise, prepare as for intramuscular injection.

(4) Intrathecal Use: The intrathecal use of penicillin in meningitis must be highly individualized. It should be employed only with full consideration of the possible irritating effects of penicillin when used by this route. The preferred route of therapy in bacterial meningitis is intravenous, supplemented by intramuscular injection.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Sterile solution may be left in refrigerator for one week without significant loss of potency.

HOW SUPPLIED

Buffered Bacipec® (penicillin G sodium) for Injection is available in vials containing
1,000,000 units x 10's vials per packet.

SIDE EFFECTS

Penicillin is a substance of low toxicity but does have a significant index of sensitization. The following hypersensitivity reactions have been reported: skin rashes ranging from maculopapular eruptions to exfoliative dermatitis; urticaria; and reactions resembling serum sickness, including chills, fever, edema, arthralgia and prostration. Severe and occasionally fatal analphylaxis has occurred.
Hemolytic anemia, leucopenia, thrombocytopenia, nephropathy, and neuropathy are rarely observed adverse reactions and are usually associated with high intravenous dosage.
Cardiac arrhythmias and cardiac arrest may also occur. (High dosage of penicillin G sodium may result in congestive heart failure due to high sodium intake.)
The Jarisch-Herxheimer reaction has been reported in patients treated for syphilis.

DRUG INTERACTIONS

Concurrent administration of bacteriostatic antibiotics (e.g., erythromycin, tetracycline) may diminish the bactericidal effects of penicillins by slowing the rate of bacterial growth. Bactericidal agents work most effectively against the immature cell wall of rapidly proliferating microorganisms.
Penicillin blood levels may be prolonged by concurrent administration of probenecid which blocks the renal tubular secretion of penicillins.
Displacement of penicillin from plasma protein binding sites will elevate the level of free penicillin in the serum.

WARNINGS

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/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 penicillin, cephalosporins, or other allergens. If an allergic reaction occurs, the drug should be discontinued and the appropriate therapy instituted. Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management including intubation, should also be administered as indicated.

PRECAUTIONS

General: Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma.

Intramuscular Therapy: Care should be taken to avoid intravenous or accidental intra-arterial administration or injection into or near major peripheral nerves or blood vessels, since such injections may produce neurovascular damage. Particular care should be taken with IV administration because of the possibility of thrombophlebitis.
In streptococcal infections, therapy must be sufficient to eliminate the organism (10 days minimum), otherwise the sequelae of streptococcal disease may occur.
Cultures should be taken following the completion of treatment to determine whether streptococci have been eradicated.
Whenever allergic reactions occur, penicillin should be withdrawn unless in the opinion of the physician, the condition being treated is life threatening and amenable only to penicillin therapy.

Teratogenic Effects: 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. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Penicillins are excreted in human milk. Caution should be exercised when penicillin G is administered to a nursing woman.

Pediatric Use: Penicillins are excreted largely unchanged by the kidney. Because of incompletely developed renal function in infants, the rate of elimination will be slow. Use caution in administering to newborns and evaluate organ system function frequently.

Geriatric Use: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Storage: Kept in well– closed containers and stored in a dry place below 30°C, away from children.

Validity: Three years.

MANUFACTURED BY:

CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.
No. 88 Yangzi Road, Shijiazhuang City, China.

For: **CLARION MEDICALS LTD.**
23A, Afolabi Lesi Street, Ilupeju, Lagos, Nigeria.

1. NAME OF THE MEDICINAL PRODUCT

Product name:Benzylpenicillin sodium for injection 1.0 Mega/vial

Pharmaceutical form:Powder for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Components	Unit dose	Function
Benzylpenicillin Sodium	Benzylpenicillin sodium 1.0 Mega	Active ingredient

3.PHARMACEUTICAL FORM

Powder for injection

4.Clinical particulars

4.1Therapeutic indications

Aqueous penicillin G (parenteral) is indicated in the therapy of severe infections caused by penicillin G-susceptible microorganisms when rapid and high penicilin levels are required in the conditions listed below. Therapy should be guided by bacteriological studies (including susceptibility tests) and by clinical response.

Posology and method of administration

Severe infections due to Susceptible Strains of Streptococci, Pneumococci, and Staphylo-coccl: bacteremia, pheumonia, endocarditis, pericarditis, empyema, meningitis and other severe infections- a minimum of 5 million units daily.

Syphilis: Aqueous penicillin G may be used in the treatment of acquired and congenital syphilis but because of the necessity of frequent dosage, hospitalization is recommended. Dosage and duration of therapy will be determined by age of patient and stage of the disease. Gonorrheal endocarditis: a minimum of 5 million units daily.

Meningococcic meningitis: 1-2 million units intramuscularly every 2 hours, or continuous IV drip of 20- 30 million units/day.

Actinomycosis: 1-6 million units/day for cervicofacial cases, 10-20 million units/day for thoracic and abdominal disease.

Clostridial infections: 20 million units/day penicillin is adjunctive therapy to antitoxin,

Fusospirochetal infections: severe infections of oropharynx, lower respiratory tract, and genital area 5-10 million units/day.

Rat-bite fever (Spirillum minus or Streptobacillus moniliformis): 12-15 million unit/day for 3-4 weeks.

Listeria infections (Listeria monocytogenes): Neonates- 500,000 to 1 million units/day

Adults with meningitis- 15-20 million units/day for 2 weeks. Adults with endocarditis -15-20 million units/day for 4 weeks. Pasteurella infections (Pasteurella multocida):

Bacteremia and meningitis- 4-6 million units/day for 2 weeks .

Erysipeloid (Erysipelothrix insidiosa) Endocarditis: 2-20 milion units/day for 4-6 weeks. Gram-negative bacillary infections (E. coli , Enterobacter aerogenes, A. faecalis, Salmonella,Shigella and Proteus mirabilis): Bacteremia- 20-80 million units/day.

Diphtheria: carrier state- 300,000- -400,000 units of penicillin/day in divided doses for 10-12 days.

Anthrax: A minimum of 5 million units of penicillin/day in divided doses until cure is effected.

THE 20,000,000 UNIT DOSAGE MAY BE ADMINISTERED BY INTRAVENOUS INFUSION ONLY.

(1) Intramuscular Injection: Keep total volume of injection small. The intramuscular route is the preferred route or administration. Solutions containing up to 1 00,000 units of penicillin per mL of diluent may be used with a minimum of discomfort. Greater concentration of penicillin G per mL is physically possible and may be employed where therapy demands. When large dosages are required,it may be advisable to administer aqueous solutions of penicillin by means of continuous intravenous drip.

(2) Continuous Intravenous Drip: Determine the volume of fluid and rate of its administration required by the patient in a 24 hour period in the usual manner for fluid therapy and add the appropriate daily dosage of penicillin to this fluid. For example, if an adult patient requires 2 liters of fluid in 24 hours and a daily dosage of 10 million units of penicillin, add 5 million units to 1 liter and adjust the rate of flow so the liter will be infused in 12 hours.

(3) Intrapleural or Other Local Infusion: If fluid is aspirated, give infusion in a volume equal to 1/4 or 1/2 the amount of fluid aspirated, otherwise, prepare as for intramuscular injection.

(4) Intrathecal Use: The intrathecal use of penicillin in meningitis must be highly individualized. It should be employed only with full consideration of the possible irritating effects of penicillin when used by this route. The preferred route of therapy in bacterial meningitis is intravenous, supplemented by intramuscular injection.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Sterile solution may be left in refrigerator for one week without significant loss of potency.

Contraindications

Allergy to penicillins. Hypersensitivity to any ingredient of the preparation.

Cross allergy to other beta-lactams such as cephalosporins should be taken into account

Special warnings and precautions for use

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/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 penicillin, cephalosporins, or other allergens.If an

allergic reaction occurs, the drug should be discontinued and the appropriate therapy instituted.Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen,intravenous steroids, and airway management including intubation, should also be administered as indicated.

General: Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma.

Intramuscular Therapy: Care should be taken to avoid intravenous or accidental intra-arterial administration or injection into or near major peripheral nerves or blood vessels, since such injections may produce neurovascular damage. Particular care should be taken with IV administration because of the possibility of thrombophlebitis.

In streptococcal infections, therapy must be sufficient to eliminate the organism (10 days minimum),otherwise the sequelae of streptococcal disease may occur.

Cultures should be taken following the completion of treatment to determine whether streptococci have been eradicated.

Whenever allergic reactions occur, penicillin should be withdrawn unless in the opinion of the physician, the condition being treated is life threatening and amenable only to penicillin therapy.

Interaction with other medicinal products and other forms of interaction

Concurrent administration of bacteriostatic antibiotics (e.g., erythromycin, tetracycline) may diminish the bactericidal effects of penicillins by slowing the rate of bacterial growth.

Bactericidal agents work most effectively against the immature cell wall of rapidly proliferating microorganisms.

Penicillin blood levels may be prolonged by concurrent administration of probenecid which blocks the renal tubular secretion of penicillins.

Displacement of penicillin from plasma protein binding sites will elevate the level of free penicillin in the serum.

Pregnancy and Lactation

Teratogenic Effects: 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. This drug should be used during pregnancy only if clearly needed.

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

Effects on ability to drive and use machines

Not applicable.

Undesirable effects

Penicillin is a substance of low toxicity but does have a significant index of sensitization. The following