BIOEDIC INJECTION

FORTIFIED PROCAINE PENICILLIN BP 4 MEGA

Vial/ Flacons

Each vial contains /Cheque f lacon contient:
PROCAINE PENICILLIN BP AND BENZYLPENICILLIN SODIUM BP

equivalent to / equivalent ta

Procaine Penicillin BP	3.0 g (abt. / eqv.3.000.000 I.U / Vial)
Benzylpenicillin Sodium BP	0.6 g (abt. / eqv.1.000.000 I.U / Vial)

For i.m.Injection only. Suspend in 8ml of water for injections immediately before use. Shake well. Store below 30C.

Seulement pour des inj.i.m. Suspendre en 8ml d'Eau pour des injections immediatement avant usage, bien agiter, Conserver en dessous de 30C.

MEDICINES SHOULD BE KEPT OUT OF THE REACH OF CHILDREN

Manufatured For: Clarion Medicals Limited. 23A, Afolabi, Lesi Street, Ilupeju, Lagos, Nigeria.
Manufactured by: CSPC Zhongnuo Pharmaceuticals (Shihiazhuang) No 88 Yangzi Road Shijiazhuang City China

NAFDAC REG. NO.: A4- 4482

Man.: 2021-08
Exp.: 2024-08
Lot.: 619210805

BIOEDIC INJECTION
FORTIFIED PROCAINE PENICILLIN
4 MEGA I.U.

Man.: 2021-08
Exp.: 2024-08
Lot.: 6192108O5

NAFDAC REG. NO.: A4- 4482

BIOEDIC INJECTION

FORTIFIED PROCAINE PENICILLIN BP 4 MEGA

1x10 Vials/ Flacons

Each vial contains/Cheque f lacon contient:
PROCAINE PENICILLIN BP AND BENZYLPENICILLIN SODIUM BP
equivalent to / equivalent ta

Procaine Penicillin BP	3.0 g (abt. / eqv.3.000.000 I.U / Vial)
Benzylpenicillin Sodium BP	0.6 g (abt. / eqv.1.000.000 I.U / Vial)

For i.m.Injection only. Suspend in 8ml of water for injections immediately before use. Shake well. Store below 30C.

Seulement pour des inj.i.m. Suspendre en 8ml d'Eau pour des injections immediatement avant usage, bien agiter, Conserver en dessous de 30C.

MEDICINES SHOULD BE KEPT OUT OF THE REACH OF CHILDREN

Manufatured For: Clarion Medicals Limited. 23A, Afolabi, Lesi Street, Ilupeju, Lagos, Nigeria.

Manufactured by:
CSPC Zhongnuo Pharmaceuticals (Shijiazhuang) Co., Ltd.
No 88 Yangzi Road Shijiazhuang City China

1 X 10 Vials
Store Below 30°c

BIOEDIC INJECTION
FORTIFIED PROCAINE PENICILLIN
4 MEGA I.U.

BIOEDIC INJECTION
FORTIFIED PROCAINE PENICILLIN BP 4 MEGA
1x10 Vials/ Flacons
Each vial contains/Cheque f lacon contient:
PROCAINE PENICILLIN BP AND BENZYLPENICILLIN SODIUM BP
equivalent to / equivalent ta
Procaine Penicillin BP 3.0 g (abt. / eqv.3.000.000 I.U / Vial)
Benzylpenicillin Sodium BP 0.6 g (abt. / eqv.1.000.000 I.U / Vial)
For i.m.Injection only. Suspend in 8ml of water for injections immediately before use. Shake well. Store below 30C.
Seulement pour des inj.i.m. Suspendre en 8ml d'Eau pour des injections immediatement avant usage, bien agiter, Conserver en dessous de 30C.
MEDICINES SHOULD BE KEPT OUT OF THE REACH OF CHILDREN
Manufatured For: Clarion Medicals Limited. 23A, Afolabi, Lesi Street, Ilupeju, Lagos, Nigeria.

1. NAME OF THE MEDICINAL PRODUCT

Product name: Fortified procaine benzylpenicillin for injection 4.0 Mega

Pharmaceutical form:Powder for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains procaine benzylpenicillin 3.0 Mega, benzylpenicillin sodium 1.0 Mega.

3.PHARMACEUTICAL FORM

Powder for injection

4.Clinical particulars

4.1Therapeutic indications

Aqueous BIOEDIC (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 penicilin 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 (L isteria monocytogenes).

Meningitis and endocarditis.

Pasteurella infections (Pasteurella multocida).

Bacteremia and meningitis.

Rat-bite fever (Spirilum minus or Streptobacillus moniliformis)

Gonorrheal endocarditis and arthritis (N. gonorrhoeae) Syphillis (T. pallidum) including congenital syphilis.

Meningococcic meningitis

4.2 Posology and method of administration

BIOEDIC is administered by deep intramuscular injection in usual does of 0.6 to 1.2g daily.

4.3 Contraindications

A previous hypersensitivity reaction to any benzylpenicillin or procaine is a contraindication.

4.4 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 intections, 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.

4.5 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.

4.6 Pregnancy and Lactation

Human experience with the penicillins during pregnancy has not shown any positive evidence of adverse effects on the foetus. There are, however, no adequate and well controlled studies in pregnant women showing conclusively that harmful effects of these agents on the foetus can be excluded.
The medicine is excreted in breast milk in concentrations lower than plasma levels. As safety to newborn infants has not been established, it is not recommended for breast feeding mothers unless the benefits outweigh any potential risk.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable 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 raniging 「 rol laculopapular erupliors lo exfolialive derrlalilis; urlicaria; and reaclions resernbling seru1 sickness, including chills, fever, ederra, arlhralgia 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.

4.9 Overdose

It has the potential to cause neuromuscular hyperirritability or convulsive seizures. Management of overdosage should include monitoring of electrolyte balance, cardiovascular status and renal function. Penicillins are not readily removed by dialysis.

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties Pharmacotherapeutic

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 bacteria, such as tonsillitis, scarlet fever, crysipelas, furuncles and carbuncles. It is also effective for syphilis, vincent's angina and gonorrhea.

5.2 Pharmacokinetic properties

There are no preclinical safety data of relevance to the prescriber that are additional to those included in other sections.

5.3 Preclinical safety data

Not applicable.

6.PHARMACEUTICAL PARTICULARS

6.1 List of excipients

There is no excipients, so not applicable.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened 36 months.

6.4 Special precautions for storage

Stored at a temperature not exceeding 30°C in a dry place.

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

18ml Mould vial fitted with a butyl rubber stopper and aluminium cap.

6.6 Special precautions for disposal <and other handling>

Not applicable.

7.<APPLICANT/MANUFACTURER>

Name and address:

Name:CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.

Address:No.88 Yangzi Road, Shijiazhuang City, Hebei Province, China

Tel:+86-311-66575339

Fax:Not applicable

Email:licuikun_2013@126.com