Bosch

For Medical Professional only

Boschoclox Injection

(Cloxacillin Sodium)

(Manufacturer's Specs.)

بوشوکلوکس انجکشن

(کلوکساسلین سوڈیم)

DESCRIPTION:
Cloxacillin sodium is a white, crystalline powder. Its chemical name is 6-[[[3-(2-Chlorophenyl)-5-methyl-4isoxazolyl[carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, sodium salt. Its empirical formula is $C_{19}H_{17}ClN_3NaO_5S \cdot H_2O$ and molecular weight is 475.88

COMPOSITION:
Each Boschoclox 250mg vial contains:
Cloxacillin Sodium U.S.P.
eq. to Cloxacillin Base.....250mg

CLINICAL PHARMACOLOGY:
Pharmacodynamic Properties:
Pharmacotheraputic group: semisynthetic penicillin antibiotic or Beta-lactamase resistant penicillins ATC code: J01CF02

Mechanism of Action:
Boschoclox exerts a bacterial action against susceptible microorganisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptides.

Microbiology:
Cloxacillin demonstrates activity against strains of beta-hemolytic streptococci, pneumococci, penicillin G sensitive staphylococci and, due to its resistance to penicillinase, penicillin G resistant (β-lactamase producing) staphylococci. Cloxacillin displays less intrinsic antibacterial activity and a narrower spectrum than penicillin G.

Pharmacokinetic Properties
Boschoclox is stable in an acid medium and is approximately 50% absorbed orally. After an oral dose of 500mg Boschoclox, a peak serum level of about 8 micrograms/mL is reached in about 1 hour. The serum level after i.m. Boschoclox is approximately twice that obtained when the same dose is given orally to fasting adults. Food in the stomach or small intestine reduces absorption and peak serum levels are approximately 50% those obtained after fasting. Once absorbed, approximately 94% are bound to plasma proteins. After oral administration, roughly 20% of the dose is excreted in the urine, together with one or more active metabolites as yet unidentified. The half life of elimination is about 30 minutes.

THERAPEUTIC INDICATIONS:
The treatment of beta-hemolytic streptococcal and pneumococcal infections as well as staphylococcal infections (including those caused by beta-lactamase producing organisms). In severe staphylococcal infections (septicaemia, osteomyelitis, endocarditis, pneumonia) or when staphylococci are suspected and treatment is required before sensitivity results are available.

DOSAGE AND ADMINISTRATION:
Adults: 250 to 500 mg i.m. or i.v. every 6 hours. I.V. dosage may be increased in serious infections. Maximum dosage for adults is 6 g/day.

Children (up to 20 kg): 25 to 50 mg/kg/day into 4 equal doses administered i.m. or i.v. every 6 hours.

METHOD OF ADMINISTRATION:
For IM/IV:
Shake well to dissolve. Administer total contents of vial by slow infusion over 2-4 minutes.

IV Infusion:
Shake well to dissolve. Administer total contents of vial by slow infusion over 30-40 minutes.

RECONSTITUTION:
Tap vial gently to loosen powder. Use only Sterile Water for injection. Immediate use of the reconstituted solution is recommended.

For IM use: Reconstitute by adding 1.9 ml of sterile water for injection to 250 mg for concentration of 125 mg/ml.

For IV Use: Reconstitute by adding 4.9 ml of sterile water for injection to 250 mg for concentration of 50 mg/ml.

For IV Infusion: Reconstitute by adding 3.4 ml of sterile water for injection to 1000 mg for concentration of 250 mg/ml.

CONTRAINDICATIONS:
Boschoclox for Injection is contraindicated in patients who are hypersensitive to this drug, to penicillin, or to cephalosporins or to any component of the container.

WARNINGS AND PRECAUTIONS:
Hematologic, Renal and Hepatic:
During long-term therapy, renal, hepatic and hematopoietic functions should be checked periodically.

Immune:
Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients receiving penicillin or cephalosporin therapy. These reactions are more apt to occur in individuals with a history or sensitivity to multiple allergens. Careful inquiry should be made concerning previous hypersensitivity to reactions to penicillins, cephalosporins or other allergens. If allergic or anaphylactic reactions occurs, discontinue treatment and administer the usual agents, e.g. antihistamines, pressor amines, corticosteroids.

Neurologic:
The passage of any penicillin from blood into brain is facilitated by inflamed meninges and during cardiopulmonary bypass. In the presence of such factors, particularly in renal failure when high serum concentration can be attained, CNS adverse effects including myoclonia, convulsive seizures and depressed consciousness can be expected.

Sensitivity/Resistance:
Candidiasis and other superinfections may occur, especially in debilitated and malnourished patients, or those with low resistance to infection due to corticosteroids, immunosuppressors or irradiation. If superinfection occurs, institute appropriate measures.

DRUG INTERACTIONS:
Probenecid
As with other penicillins, concurrent administration of probenecid enhances the serum concentration of cloxacillin.

ADVERSE EFFECTS:
Gastrointestinal: Nausea, vomiting, epigastric discomfort, flatulence and loose stools have been noted in some patients.
Hematologic: Eosinophilia, leucopenia, anemia, thrombocytopenia, thrombocytopenic, purpura, neutropenia and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Thrombophlebitis has occurred during the course of i.v. therapy. Mildly elevated SGOT level (less than 100 units) have been reported.
Immune: Allergic reactions (rash, urticaria) including wheezing and sneezing have been reported.

SPECIFIC POPULATION:
Pregnancy:
Safety in pregnancy has not yet been established.

Pediatrics:
Experience in premature and newborn infants is limited. Cautious administration of the drug to such patients and frequent evaluation of organ system function is recommended.

OVERDOSE:
Treatment is likely needed only in patients with severely impaired renal function, since patients with normal kidneys excrete penicillins at a fast rate. No specific treatment can be recommended. In patients with severe allergic reactions, general supportive measures (if the patient is in shock) or symptomatic therapy similar to that applied in all cases of hypersensitivity are recommended.

COMPATIBILITIES:
Boschoclox for Injection is compatible at concentrations of 1 and 2 mg/mL up to 12 hours at controlled room temperature not exceeding 25°C in dextrose 5% in water, fructose 10% in water or normal saline, M/6 sodium lactate, Lactated Ringer's invert sugar 10% in water or normal saline.

PRESENTATION:
Boschoclox 250mg: Cloxacillin for injection is supplied as a dry powder in vial containing Cloxacillin sodium U.S.P. eq. to 250mg Cloxacillin base.

Storage and Instructions:
Protect from heat, sunlight & moisture.
Store at controlled room temperature (15°C-30°C).
The expiration date refer to the product correctly stored at the required condition.
Reconstituted solution may be stored for up to 24 hours at controlled room temperature not exceeding 25°C or in refrigerator at 2°- 8°C for up to 48 hours. Discard unused portion.
Keep out of the reach of children.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

بچوں/وریدی استعمال کے لئے۔
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:-
دھوپ گرمی اور نمی سے محفوظ کمرے کے درجہ حرارت (۱۵-۳۰ ڈگری سینٹی گریڈ) پر رکھیں۔
تیار شدہ محلول کمرے کے درجہ حرارت (۲۵ ڈگری سینٹی گریڈ سے کم) پر رکھنے کی صورت میں ۲۴ گھنٹے یا ریفریجریٹر میں ۲-۸ ڈگری سینٹی گریڈ پر ۴۸ گھنٹے تک قابل استعمال رہتا ہے۔ بچ جانے والا محلول ضائع کر دیں۔
بچوں کی پہنچ سے دُور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt) Ltd.
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan

ISO 9001:2015 Certified Company