Bristol : Polycillin-N sodium ampicillin for intramuscular or intravenous injection.

Contributors

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BRISTOL

POLYCILLIN-N™

SODIUM AMPICILLIN

FOR INTRAMUSCULAR OR INTRAVENOUS INJECTION

Description: POLYCILLIN-N (sodium ampicillin), a synthetic penicillin with an extended spectrum, has been shown to be effective against the usual penicillin-susceptible Gram-positive organisms plus many common Gram-negative pathogens.

The following bacteria have been shown in **in vitro** studies to be sensitive to ampicillin:

GRAM-POSITIVE ORGANISMS: hemolytic and nonhemolytic streptococci, **D. pneumoniae,** nonpenicillinase-producing staphylococci, Clostridia spp., **B. anthracis, C. xerosis,** and most strains of enterococci.

GRAM-NEGATIVE ORGANISMS: **H. influenzae, B. funduliformis, N. gonorrhoeae, N. meningitidis, Br. abortus, Br. melitensis, Proteus mirabilis,** and many strains of Salmonella, Shigella and E. coli.

It has proved effective in the treatment of many infections previously beyond the scope of penicillin therapy. Its antimicrobial action is bactericidal, and only a small percentage of the antibiotic is bound by blood serum. The drug does not resist destruction by penicillinase. It is stable in the presence of gastric acid and is well absorbed from the gastrointestinal tract.

Indications: This compound is particularly indicated for the treatment of infections due to susceptible strains of Gram-negative bacteria (including Shigella, **S. typhosa** and other Salmonella, **E. coli, H. influenzae,** and **P. mirabilis**). Other indications include infections due to such susceptible Gram-positive organisms as streptococci, pneumococci, and nonpenicillinase-producing staphylococci.

It is particularly indicated in urinary tract infections, respiratory tract infections, and gastrointestinal tract infections.

It is advisable to reserve the parenteral form of this drug for moderately severe and severe infections and for patients who are unable to take the oral forms. A change to oral POLYCILLIN® (ampicillin trihydrate) may be made as soon as appropriate.

Contraindications: A history of serious allergic reaction to penicillin contraindicates the use of this agent. It is also contraindicated in infections caused by penicillinase-producing staphylococci or other penicillinase-producing agents.

Precautions: As with any penicillin preparation, the possibility of an allergic response to this drug is more likely in a hypersensitive individual. Careful inquiry about past reactions to penicillin or other allergens is indicated before the drug is used. Should an allergic reaction to ampicillin occur the drug should be discontinued and the patient treated with the usual agents (antihistamines, pressor amines, corticosteroids).

As with any potent drug, periodic assessment of organ system function, including renal, hepatic, and hematopoietic, should be made during prolonged therapy. Experience with POLYCILLIN-N (sodium ampicillin) in premature and newborn infants is limited. Caution should be exercised in administration of the drug to such patients and frequent evaluation of organ system function is recommended.

The possibility of the occurrence of superinfections with mycotic organisms or other pathogens should be kept in mind when using sodium ampicillin as with other antibiotics. If superinfection occurs during therapy appropriate measures should be taken.

In the treatment of complications of gonorrheal urethritis, such as prostatitis and epididymitis, prolonged and intensive therapy is recommended. Cases of gonorrhea with a suspected primary lesion of syphilis should have dark-field examinations before receiving treatment. In all other cases where concomitant syphilis is suspected monthly serological tests should be made for a minimum of three months.

Safety for use in pregnancy has not been established.

It is advisable to reserve the parenteral form of this drug for moderately severe and severe infections and for patients who are unable to take the oral forms.

Adverse Reactions: To date, reactions have been infrequent and have included skin rash, pruritus and urticaria as well as gastrointestinal disturbances with oral use (nausea, vomiting, diarrhea). Anaphylactic reactions have also occurred.

A few instances of moderate elevation of serum glutamic oxaloacetic transaminase (SGOT) have been observed. The significance of this observation is unknown. Mild transitory SGOT elevations have been observed in individuals receiving larger (two to four times) than usual and oft-repeated intramuscular injections. Evidence indicates that glutamic oxaloacetic transaminase (GOT) is released at the site of intramuscular injection of sodium ampicillin and that the presence of increased amounts of this enzyme in the blood does not necessarily indicate liver involvement.

Dosage: Infections of the ear, nose, throat and lower respiratory tract due to streptococci, pneumococci and nonpenicillinase-producing staphylococci; **and also infections of the upper and lower respiratory tract due to H. influenzae.**

Adults: 250-500 mg. every 6 hours.

Children: 25-50 mg./Kg./day in equally divided doses at 6-hour intervals.

Infections of the genitourinary tract caused by sensitive Gram-negative and Gram-positive bacteria.

Adults: 500 mg. every 6 hours.

Children: 50 mg./Kg./day in equally divided doses at 6-hour intervals.

Urethritis due to N. gonorrhoeae.

Adults: 250 mg. every 12 hours.

(In the treatment of complications of gonorrheal urethritis, such as prostatitis and epididymitis, prolonged and intensive therapy is recommended. Cases of gonorrhea with a suspected primary lesion of syphilis should have dark-field examinations before receiving treatment. In all other cases where concomitant syphilis is suspected monthly serological tests should be made for a minimum of three months.)

Infections of the gastrointestinal tract.

Adults: 500 mg. every 6 hours.

Children: 50 mg./Kg./day in equally divided doses at 6-hour intervals.

Larger doses may be required for stubborn or severe infections. The children's dosage is intended for individuals whose weight will not cause a dosage to be calculated greater than that recommended for adults. Children weighing more than 20 Kg. should be dosed according to the adult recommendations.

Bacterial Meningitis: Children with bacterial meningitis (caused by **N. meningitidis** or **H. influenzae**) have been successfully treated with doses of 100-200 mg./Kg./day. A few adults have been successfully treated for bacterial meningitis with doses ranging from 8 to 14 Gm. daily. This treatment has been initiated with intravenous drip therapy and continued with frequent (every 3-4 hours) intramuscular therapy. The doses for other infections may be given by either the intravenous or intramuscular route.

It should be recognized that in the treatment of chronic urinary tract and intestinal infections, frequent bacteriological and clinical appraisal is necessary. Smaller doses than those recommended above should not be used. Even higher doses may be needed at times. In stubborn infections therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

The treatment of Gram-negative infections is often complicated by the emergence of resistant organisms (**Aerobacter aerogenes,** Pseudomonas, etc.) which may cause superinfections. The possibility of such an occurrence should be kept in mind with the use of POLYCILLIN-N (sodium ampicillin).

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. A minimum of 10 days' treatment is recommended for any infection caused by hemolytic streptococci to help prevent the occurrence of acute rheumatic fever and glomerulonephritis.

A change to oral POLYCILLIN (ampicillin trihydrate) may be made as soon as appropriate.

Directions for Use: For Intramuscular Use: Each vial (of either size) is to be reconstituted with 1.2 ml. of Sterile Water for Injection U.S.P., and the entire contents withdrawn. The solution must be used within one hour after reconstitution.

For Direct Intravenous Administration: Each vial (of either size) is to be reconstituted with 5 ml. of Sterile Water for Injection, U.S.P., and the entire contents withdrawn. The dose should be injected over a period of 3 to 5 minutes. The solution must be used within one hour after reconstitution.

For Administration by Intravenous Drip: Stability studies on sodium ampicillin at concentrations of 2 mg./ml. and 30 mg./ml. in various intravenous solutions indicate the drug will lose less than 10% activity at room temperature (70°F.) for the time periods stated:

Isotonic sodium chloride	8 hours
Five percent dextrose in water	4 hours
Five percent dextrose in 0.4% sodium chloride solution	4 hours
Ten percent invert sugar in water	4 hours
M/6 sodium lactate solution (in conc. of 30 mg./ml.)	4 hours

Supply: POLYCILLIN-N (sodium ampicillin) For Injection. Sodium ampicillin equivalent to 250 or 500 mg. ampicillin per vial.

List 79962—250 mg. vial.

List 79964—500 mg. vial.

Also available:

POLYCILLIN (ampicillin trihydrate) Capsules. Ampicillin trihydrate equivalent to 250 mg. ampicillin per capsule.

List 79924—bottles of 24.

List 79925—bottles of 100.

POLYCILLIN (ampicillin trihydrate) for Oral Suspension. Each 5 ml. of reconstituted suspension contains ampicillin trihydrate equivalent to 125 mg. ampicillin.

List 79883—60 ml. bottle.

List 79886—80 ml. bottle.

BRISTOL LABORATORIES, Syracuse, New York

Division of Bristol-Myers Company

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