APP

45960D/Revised: October 2010

BACITRACIN
FOR INJECTION, USP

Rx only

For Intramuscular Use

WARNING

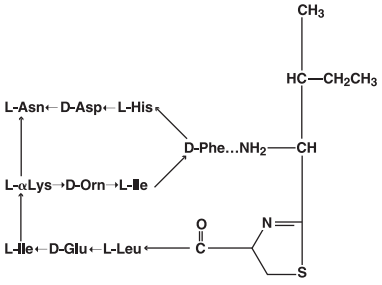
Nephrotoxicity: Bacitracin in parenteral (intramuscular) therapy may cause renal failure due to tubular and glomerular necrosis. Its use should be restricted to infants with staphylococcal pneumonia and empyema when due to organisms shown to be susceptible to bacitracin. It should be used only when adequate laboratory facilities are available and when constant supervision of the patient is possible.

Renal function should be carefully determined prior to and daily during therapy. The recommended daily dose should not be exceeded and fluid intake and urinary output maintained at proper levels to avoid kidney toxicity. If renal toxicity occurs the drug should be discontinued. The concurrent use of other nephrotoxic drugs, particularly streptomycin, kanamycin, polymyxin B, polymyxin E (colistin), and neomycin should be avoided.

DESCRIPTION:

Bacitracin for Injection, USP is an antibiotic for intramuscular administration. Bacitracin is derived from cultures of *Bacillus licheniformis*. It is a white to pale buff, hygroscopic powder, odorless or having a slight odor. It is freely soluble in water; insoluble in acetone, chloroform, and ether. While soluble in alcohol, methanol, and glacial acetic acid, there is some insoluble residue. It is precipitated from its solutions and inactivated by many of the heavy metals.

The structural formula is:



bacitracin A

$C_{66}H_{103}N_{17}O_{16}S$ **M.W. 1422.71**

Bacitracin is comprised of a polypeptide complex and Bacitracin A is the major component in this complex.

CLINICAL PHARMACOLOGY:
Bacitracin, an antibiotic substance derived from cultures of *Bacillus licheniformis* exerts pronounced antibacterial action *in vitro* against a variety of gram-positive and a few gram-negative organisms. However, among systemic diseases, only staphylococcal infections qualify for consideration of bacitracin therapy. Bacitracin is assayed against a standard and its activity is expressed in units, 1 mg having a potency of not less than 50 units.

Susceptibility plate testing
If the Kirby-Bauer method of disk susceptibility is used, a 10 unit bacitracin disk should give a zone of over 13 mm when tested against a bacitracin-susceptible strain of *Staphylococcus aureus*. Absorption of bacitracin following intramuscular injection is rapid and complete. A dose of 200 or 300 units/kg every 6 hours gives serum levels of 0.2 to 2 mcg/mL in individuals with normal renal function. The drug is excreted slowly by glomerular filtration. It is widely distributed in all body organs and is demonstrable in ascitic and pleural fluids after intramuscular injection.

INDICATIONS AND USAGE:
In accord with the statements in the "Warning Box" the use of intramuscular bacitracin is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug.

CONTRAINDICATIONS:
This drug is contraindicated in those individuals with a history of previous hypersensitivity or toxic reaction to it.

PRECAUTIONS:
See "Warning Box" for precautions in regard to kidney toxicity associated with intramuscular use of bacitracin.

Adequate fluid intake should be maintained orally, or if necessary, by parenteral method.

As with other antibiotics, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be instituted.

ADVERSE REACTIONS:
Nephrotoxic reactions
Albuminuria, cylindruria, azotemia. Rising blood levels without any increase in dosage.

Other reactions
Nausea and vomiting. Pain at sight of injection. Skin rashes.

DOSAGE AND ADMINISTRATION:
TO BE ADMINISTERED INTRAMUSCULARLY ONLY
Infant dose
For infants under 2500 grams - 900 units/kg/24 hours, in 2 or 3 divided doses. For infants over

2500 grams - 1,000 units/kg/24 hours, in 2 or 3 divided doses. Intramuscular injections of the solution should be given in the upper outer quadrant of the buttocks, alternating right and left and avoiding multiple injections in the same region because of the transient pain following injection.

Preparation of Solutions

Should be dissolved in sodium chloride injection containing 2 percent procaine hydrochloride. The concentration of the antibiotic in the solution should not be less than 5,000 units per mL nor more than 10,000 units per mL.

Diluents containing parabens should not be used to reconstitute bacitracin; cloudy solutions and precipitate formation have occurred.

Reconstitution of the 50,000 unit vial with 9.8 mL of diluent will result in a concentration of 5,000 units per mL.

Solutions are stable for one week when stored in a refrigerator 2° to 8°C (36° to 46°F).

HOW SUPPLIED:

Product No.	**NDC No.**	
302930	63323-329-30	Bacitracin for Injection, USP, 50,000 units per vial, packaged individually.
302931	63323-329-31	Bacitracin for Injection, USP, 50,000 units per vial, 10 vials per tray.

Vial stoppers do not contain natural rubber latex.

Store the unreconstituted product in a refrigerator 2° to 8°C (36° to 46°F).

APP Pharmaceuticals, LLC
Schaumburg, IL 60173

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