PRESCRIBING INFORMATION

BaciJect

Bacitracin for injection U.S.P.

Powder for Solution

Antibiotic

SteriMax Inc.
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Oakville, ON
L6H 6R4

Date of Revision:
February 8, 2016

ACTION AND CLINICAL PHARMACOLOGY

Bacitracin, an antibiotic substance derived from cultures of *Bacillus subtilis* (Tracey), 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, 1mg having a potency of not less than 50 units.

Susceptibility plate testing: If the Kirby-Bauer method of disc susceptibility is used, a 10-unit bacitracin disc should give a zone 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 six hours gives serum levels of 0.2 to 2mcg/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 CLINICAL USE

The use of intramuscular bacitracin is indicated in the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug.

Bacitracin solutions, applied locally in the form of compresses or installations, may be used once or twice daily in secondarily infected wounds, ulcers, pyodermas and other superficial skin infections and in superficial infections of the eye caused by bacitracin-susceptible organisms. Bacitracin solutions may be instilled into the nasal cavities or administered by inhalation as an aerosol in the treatment of bacitracin-susceptible infections of the upper and lower respiratory tract. In severe or extensive infections, appropriate antibacterial therapy should be given in addition to local treatment with bacitracin.

CONTRAINDICATIONS

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

WARNINGS

For Intramuscular Use

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 where 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), neomycin, and viomycin, should be avoided.

PRECAUTIONS

See "**WARNINGS**" 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 non-susceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be instituted.

ADVERSE REACTIONS

Nephrotoxic reactions: Albuminuria, Clindruria Azotemia. Rising blood levels without any increase in dosage.

Other reactions: Nausea and vomiting. Pain at site of injections. Skin rashes.

DOSAGE AND ADMINISTRATION

TO BE ADMINISTERED INTRAMUSCULARLY

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.

Reconstituted solution should be clear, pale yellow to light brown in colour and free of foreign particles.

TO BE ADMINISTERED TOPICALLY

Preparation of Solution: Solutions for topical application are prepared by dissolving bacitracin in Sterile Water for Injection or Sodium Chloride Injection in amounts to give the following concentrations:

Skin	500 units per mL
Ophthalmic Solutions	500 to 1,000 units per mL
Intranasal Therapy	250 units per mL
Aerosol	500 to 1,000 units per mL

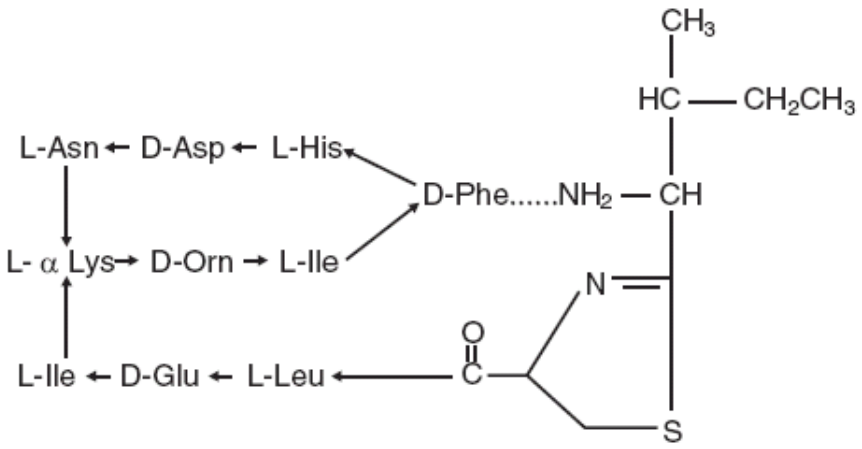
PHARMACEUTICAL INFORMATION

Drug Substance

Proper Name: bacitracin

Molecular Formula: $C_{66}H_{103}N_{17}O_{16}S$

Structural Formula:



bacitracin A

Description

Bacitracin 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.

Stability and Storage Recommendations

Store unreconstituted bacitracin in a refrigerator 2°C to 8°C. Solutions are rapidly inactivated at room temperature but are stable for one week when stored in a refrigerator 2°C to 8°C.

Availability of Dosage Forms

BaciJect, 50,000 Units/Vial, 30 mL Vial