PRESCRIBING INFORMATION

BaciJect

Bacitracin for injection U.S.P.

Powder for Solution

50,000 Units/Vial

Antibiotic

SteriMax Inc.
2770 Portland Drive,
Oakville, ON
L6H 6R4

Date of Revision:
July 30, 2018

Control No. 217226

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, 1 mg 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 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 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 instillations, 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.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of bacitracin and other antibacterial drugs, bacitracin should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

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.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing bacitracin in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

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, Cylindruria Azotemia. Rising blood levels without any increase in dosage.

Other reactions: Nausea and vomiting. Pain at site of injection. 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

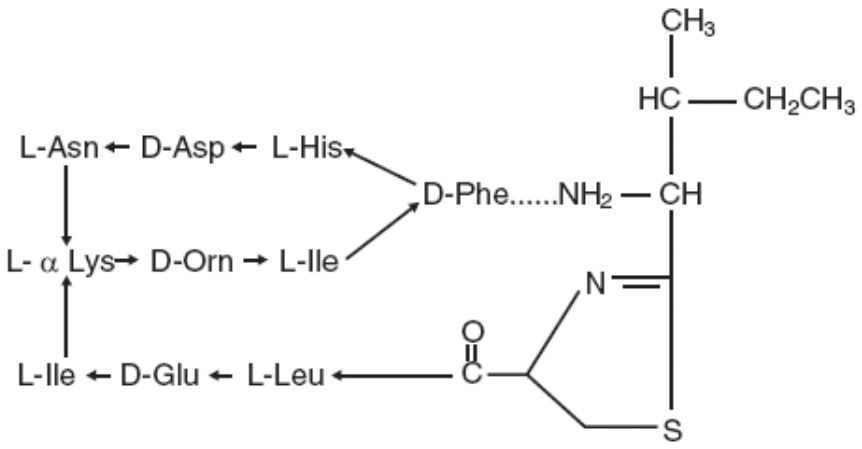
PHARMACEUTICAL INFORMATION

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

PART III: CONSUMER INFORMATION

BaciJect

This leaflet is an addition to the Prescribing Information document and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BaciJect. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
BaciJect can be used by a healthcare professional in the treatment of infants with pneumonia and empyema (accumulation of pus in the chest) caused by staphylococci (bacteria) and administered by injection in the muscle. BaciJect can also be used as a topically applied solution to treat infected wounds, ulcers, pyodermas and other superficial skin and eye infections under the supervision of a healthcare professional.

Antibacterial drugs like BaciJect treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, BaciJect should be used exactly as directed. Misuse or overuse of BaciJect could lead to the growth of bacteria that will not be killed by Baciject (resistance). This means that BaciJect may not work for you in the future. Do not share your medicine.

What it does:
BaciJect is an antibiotic that treats against a variety of organisms.

When it should not be used:
Do not take BaciJect if you are allergic (hypersensitive) to bacitracin.

What the medicinal ingredient is:
The active ingredient is bacitracin.

What the important nonmedicinal ingredients are:
There are no nonmedicinal ingredients.

What dosage forms it comes in:
BaciJect is available in a vial containing 50,000 units of bacitracin.

WARNINGS AND PRECAUTIONS

BEFORE bacitracin is administered to you or you use bacitracin topically, talk to your doctor or pharmacist if:

- You have or have had kidney problems
- Any allergies to this drug

Intramuscular bacitracin can cause kidney failure. Kidney function will be carefully determined by the doctor before and daily during your therapy. Contact your doctor immediately if the signs of kidney problems occur, with symptoms such as urinating, less than usual or not at all, blood in the urine, lower back pain, or painful urination.

As with other antibiotics, this drug may cause an overgrowth of non-susceptible organisms, including fungi. If a superinfection occurs, talk to your doctor to start appropriate treatment.

INTERACTIONS WITH THIS MEDICATION

Do not use BaciJect at the same time as other nephrotoxic drugs, especially streptomycin kanamycin, polymyxin B, polymyxin E (colistin), neomycin, and viomycin.

PROPER USE OF THIS MEDICATION

Usual dose:
Infant dose:
As determined by the doctor. For infants under 2500 grams – 900 units/kg/24 hours in 2 or 3 divided doses. For infants over 2500 grams – 1000 units/kg.24 hours in 2 or 3 divided doses, by intramuscular injection.

Preparation of Solutions for Intramuscular Use or Topical Use:
These are prepared by the doctor or pharmacist.

Overdose:
If you feel you have been administered too much bacitracin (injection), contact your attending healthcare professional.

In case of drug overdose with ingestion of topical solution, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Other reactions include nausea and vomiting, pain at injection site, and skin rashes.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Uncommon	**Kidney problems** (urinating less than usual or not at all, blood in the urine, lower back pain, or painful urination)		√	√

This is not a complete list of side effects. For any unexpected effects while taking BaciJect, contact your doctor or pharmacist.

HOW TO STORE IT

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

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be obtained by contacting the sponsor, SteriMax Inc., at **1-800-881-3550**

This leaflet is prepared by SteriMax Inc.

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