PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

BaciJect

Bacitracin for Injection USP

Sterile Lyophilized Powder for Solution, 50,000 Units/Vial, For Topical or Intramuscular Use

USP

Antibiotic

SteriMax Inc.

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Oakville, ON

L6H 6R4

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AUG 28, 2003

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JAN 24, 2023

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RECENT MAJOR LABEL CHANGES

2 CONTRAINDICATIONS	03/2021
3 SERIOUS WARNINGS AND PRECAUTIONS BOX	03/2021

TABLE OF CONTENTS

Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

BaciJect (Bacitracin for Injection USP) is indicated for:

- The treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug.
- The treatment of secondarily infected wounds, ulcers, pyodermas and other superficial skin and eye infections when used as a topically applied solution.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BaciJect and other antibacterial drugs, BaciJect 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.

Bacitracin is not indicated as an irrigation solution for intraoperative prophylaxis nor for pre-soaking of medical devices or implants prior to surgery. Anaphylactic reactions and nephrotoxicity can occur when bacitracin is used in this manner.

1.1 Pediatrics

Pediatrics (infancy: 0 – 2 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of BaciJect in infants has been established. Therefore, Health Canada has authorized an indication for infant use. (See 4.2 Recommended Dose and Dosage Adjustment)

1.2 Geriatrics

Geriatrics: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

2 CONTRAINDICATIONS

Bacitracin is contraindicated in patients:

- with a history of previous hypersensitivity or toxic reaction to it.
- who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.
- with impaired renal function, including those taking nephrotoxic drugs.

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- There have been reports of nephrotoxicity, including renal failure in patients exposed to bacitracin (see 7 WARNINGS AND PRECAUTIONS, General; Renal).
- Serious hypersensitivity and/or anaphylactic reactions have been reported in patients exposed to bacitracin (see 7 WARNINGS AND PRECAUTIONS, Immune).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Bacitracin should be used only where adequate laboratory facilities are available and when constant supervision of the patient is possible.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BaciJect and other antibacterial drugs, BaciJect 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.

Renal function should be carefully determined prior to, and daily during therapy.

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

Please refer to section 4.2 Recommended Dose and Dosage Adjustment.

4.2 Recommended Dose and Dosage Adjustment

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.

4.3 Reconstitution

INTRAMUSCULAR Use

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.

TOPICAL Use

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:

Table 1 - Reconstitution

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

4.4 Administration

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.

5 OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 2 – Dosage Forms, Strengths, Composition and Packaging

Routes of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Intramuscular, Topical	Lyophilized Powder for Solution / 50,000 Units/Vial bacitracin	None.

Packaging

BaciJect, 50,000 Units/Vial, is available in 20 mL Vial.

7 WARNINGS AND PRECAUTIONS

Please see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

General

Bacitracin is not indicated as an irrigation solution for intraoperative prophylaxis nor for pre-soaking of medical devices or implants prior to surgery. Anaphylactic reactions and nephrotoxicity can occur when

bacitracin is used in this manner.

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.

Immune

Serious hypersensitivity, including anaphylactic reactions, and allergic contact dermatitis have been reported in patients treated with bacitracin administered intramuscularly and through local exposure (see 1 INDICATIONS and 7 WARNINGS AND PRECAUTIONS, General). These reactions may occur following the first dose.

Monitoring and Laboratory Tests

Close monitoring of renal function is recommended in patients treated with bacitracin. Glomerular and tubular kidney function must be evaluated and checked before commencement of therapy, as well as during and after treatment.

Renal

Nephrotoxicity

There have been reports of nephrotoxicity in patients exposed to bacitracin via intramuscular and non-intramuscular routes, including local exposure. Bacitracin may cause renal failure due to tubular and glomerular necrosis due to high systematic absorption.

- **Bacitracin should be used only where adequate laboratory facilities are available and when constant supervision of the patient is possible**.
- Intramuscular use should be restricted to infants with Staphylococcal pneumonia and empyema due to organisms shown to be susceptible to bacitracin.
- 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.
- Patients /caregivers should stop taking BaciJect and seek immediate medical attention if the signs of kidney problems occur. Patients /caregivers should be informed of symptoms such as urinating less than usual or not at all, blood in the urine, lower back pain, or painful urination.
- If renal toxicity occurs, the drug should be discontinued.
- Concurrent use of other nephrotoxic drugs should be avoided (see 7.1.3 WARNINGS AND PRECATIONS, General; Special Populations, Pediatrics).

Sensitivity/Resistance

Development of Drug Resistant Bacteria

Prescribing BaciJect 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.

7.1 Special Populations

7.1.1 Pregnant Women

The safety and efficacy of BaciJect in pregnant women have not yet been established. No data are available.

7.1.2 Breast-feeding

It is unknown if BaciJect (Bacitracin for Injection USP) is excreted in human milk. Precaution should be exercised because many drugs can be excreted in human milk.

7.1.3 Pediatrics

Pediatrics (0 – 2 years of age): 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.

7.1.4 Geriatrics

Not applicable.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Nephrotoxic reactions: Albuminuria, Cylindruria Azotemia. Rising blood levels without any increase in dosage (see 7 WARNINGS AND PRECAUTIONS, Renal).

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

9 DRUG INTERACTIONS

9.1 Serious Drug Interactions

Serious Drug Interactions
• Do not use with nephrotoxic medications (see 2 CONTRAINDICATIONS and 9.4 Drug-Drug Interactions).

9.4 Drug-Drug Interactions

Do not use BaciJect at the same time as other nephrotoxic drugs, especially streptomycin kanamycin, polymyxin B, polymyxin E (colistin), neomycin, and viomycin (see 2 CONTRAINDICATIONS).

Interactions with other drugs have not been established.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

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*.

10.3 Pharmacokinetics

Absorption:

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.

Distribution:

BaciJect (Bacitracin for Injection USP) is widely distributed in all body organs and is demonstrable in ascitic and pleural fluids after intramuscular injection.

Elimination:

The drug is excreted slowly by glomerular filtration.

11 STORAGE, STABILITY AND DISPOSAL

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.

12 SPECIAL HANDLING INSTRUCTIONS

None.

PART II: SCIENTIFIC INFORMATION

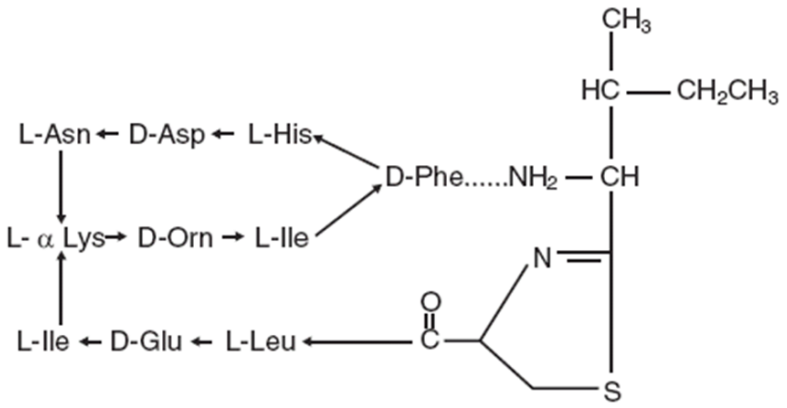
13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: bacitracin

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

Structural formula:



bacitracin A

Physicochemical properties: 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.

14 CLINICAL TRIALS

This information is not available for this drug product.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether BaciJect affects fertility in males or females.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

BaciJect

Bacitracin for Injection USP

Read this carefully before you start taking **BaciJect** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BaciJect.**

Serious Warnings and Precautions

- **Intramuscular injections of bacitracin can cause kidney failure.** Kidney failure is a condition where kidneys stop workings. Your healthcare professional will carefully monitor your Kidney function before and during your daily therapy. Contact your healthcare professional immediately and stop taking BaciJect 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. See "Serious side effects and what to do about them", below, for more information.

- **BaciJect may cause serious allergic reactions when used as an injection or when applied topically.** Contact your healthcare professional immediately and stop taking BaciJect if you think you are having an allergic reaction to BaciJect. See "Serious side effects and what to do about them", below, for more information.

What is BaciJect used for?

- BaciJect can be used to treat infants with pneumonia and empyema (accumulation of pus in the chest) caused by staphylococci (bacteria).
- BaciJect can also be used to treat infected wounds, ulcers, pyodermas and other superficial skin and eye infections.
- Antibacterial drugs like BaciJect treat only bacterial infections. They do not treat viral infections, such as the common cold.

How does BaciJect work?

BaciJect contains an antibiotic that reduces infections by:

- Stopping the growth of bacteria.
- Killing bacteria.

What are the ingredients in BaciJect?

Medicinal ingredients: 50,000 units of Bacitracin.

Non-medicinal ingredients: None.

BaciJect comes in the following dosage forms:

Lyophilized Powder for Solution, 50,000 Units/Vial

Do not use BaciJect if:

- You are allergic to bacitracin or to any other ingredients in BaciJect.
- You have impaired kidneys or are taking another drug that may impair your kidneys.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BaciJect. Talk about any health conditions or problems you may have, including if you:

- Have or have had kidney problems

Other warnings you should know about:

As with other antibiotics, this drug may cause an overgrowth of other bacteria or fungi. If you think that you have another infection (superinfection), talk to your healthcare professional.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BaciJect:

- Drugs that may also harm your kidney's such as:
  - Streptomycin kanamycin
  - Polymyxin B
  - Polymyxin E (colistin)
  - Neomycin
  - viomycin

How to take BaciJect:

- BaciJect will be given to you by a healthcare professional in a healthcare setting. Your healthcare professional will prepare the BaciJect so that it can be injected or applied to your skin.
- 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.
- You should drink lots of fluid while taking BaciJect. Your healthcare professional may need to give you additional fluids intravenously, if required.

Usual dose:

Topical application:

Your healthcare professional will prepare BaciJect based on how it will be applied. You may receive BaciJect in a compress for your skin, drops for your eye or nose, or as an aerosol to be inhaled.

Intramuscular Injection:

Infant dose:

Your healthcare professional will decide how much BaciJect to give your child, based on their weight. 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.

Overdose:

If you think you, or a person you are caring for, have taken too much BaciJect, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
Your healthcare professional will administer BaciJect. If you miss a scheduled dose talk to your healthcare professional as soon as possible.

What are possible side effects from using BaciJect?

These are not all the possible side effects you may have when taking BaciJect. If you experience any side effects not listed here, tell your healthcare professional.

Side effects include:

- nausea and vomiting,
- pain at injection site
- skin rashes.

Bacitracin may cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results. They will check your kidney function before you receive bacitracin and while you are receiving it.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
RARE			
Kidney problems: urinating less than usual or not at all, blood in the urine, lower back pain, or painful urination			√
Damage to the kidneys including kidney failure: back and abdominal pain, change in the colour of urine (pale or dark), decrease in the amount of urine produced, nausea, pain or discomfort when urinating, swelling of the legs and ankles, tiredness, weight gain.			√
Allergic reactions: difficulty breathing or swallowing, feeling			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
sick to your stomach or vomiting, hives, itchy skin, rash, skin blisters, swelling of your tongue or throat.			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) 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.

Storage:

Store BaciJect dry powder 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.

Keep out of reach and sight of children.

If you want more information about BaciJect:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (http://www.sterimaxinc.com), or by calling 1-800-881-3550.

This leaflet was prepared by SteriMax Inc.

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