PRESCRIBING INFORMATION

Bacitracin USP
(Bacitracin for Injection USP)

For Topical or Intramuscular Use in Solution

50 000 IU Sterile Powder

Pfizer Canada ULC
17,300 Trans-Canada Highway
Kirkland, Quebec H9J 2M5

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15 September 2021

Control No. 251282

PRESCRIBING INFORMATION

Bacitracin USP

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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 USP and other antibacterial drugs, Bacitracin USP 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

Bacitracin is contraindicated in patients who are hypersensitive to this drug or any ingredient in the formulation or component of the container.

Bacitracin is contraindicated in patients with impaired renal function, including those taking nephrotoxic drugs.

SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

There have been reports of nephrotoxicity, including renal failure in patients exposed to **BACITRACIN** (see **WARNINGS, Renal**).

Serious hypersensitivity and/or anaphylactic reactions have been reported in patients exposed to **BACITRACIN** (see **WARNINGS: Hypersensitivity**).

WARNINGS

General

Nephrotoxicity, hypersensitivity, and/or anaphylactic reactions have been reported in patients treated with Bacitracin administered intramuscularly and through local exposure (see **INDICATIONS AND CLINICAL USE**).

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.

Hypersensitivity

There have been reports of serious hypersensitivity, including anaphylaxis and/or allergic contact dermatitis, in patients exposed to Bacitracin following intramuscular and local administration. 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. Bacitracin may cause renal failure due to tubular and glomerular necrosis due to high systemic absorption. 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. **Bacitracin should be used only where adequate laboratory facilities are available and when constant supervision of the patient is possible**. 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. Concurrent use of other nephrotoxic drugs should be avoided.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing Bacitracin USP 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.

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

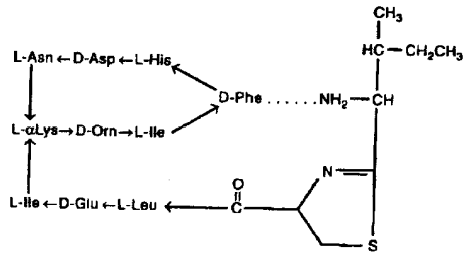
PHARMACEUTICAL INFORMATION

Drug Substance

Proper Name: Bacitracin USP

Chemical structure: $C_{66}H_{103}N_{17}O_{16}S$

Structural Formula:



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 2ºC 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:

Bacitracin USP is available in a vial containing 50,000 unit, packaged in cartons of 5's.

PART III: CONSUMER INFORMATION

BACITRACIN USP

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 BACITRACIN USP. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

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

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

When it should not be used:
Do not take BACITRACIN USP if you:
- are allergic to BACITRACIN
- are allergic to any of the other ingredients in BACITRACIN or to a component of the container.

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:
BACITRACIN USP is available in a vial containing 50,000 units, packaged in cartons of 5's.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

BACITRACIN can cause serious side effects which include:

- **Damage to the kidneys including kidney failure**. Kidney failure is a condition where your kidneys stop working.

- **Serious allergic reactions**

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 and stop taking Bacitracin 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 BACITRACIN USP 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 think you, or a person you are caring for, have taken too much Bacitracin, contact a healthcare professional, hospital emergency department, or regional poison control center 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.

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 with your doctor or pharmacist		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Uncommon	**Damage to the kidneys including kidney failure**: (back and abdominal pain, change in the colour of urine (pale or dark), decrease in 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 sick to your stomach or vomiting, hives, itchy skin, rash, skin blisters, swelling of your tongue or throat		√	√

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

HOW TO STORE IT

Store unreconstituted BACITRACIN 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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.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.

MORE INFORMATION

If you want more information about BACITRACIN:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp); the manufacturer's website (www.pfizer.ca), or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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