

BACITRACIN- bacitracin injection, powder, for solution
Pharmacia and Upjohn Company

Bacitracin for Injection, USP

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 or prevent infections that are proven or strongly suspected to be caused by bacteria.

For Intramuscular Use

WARNING

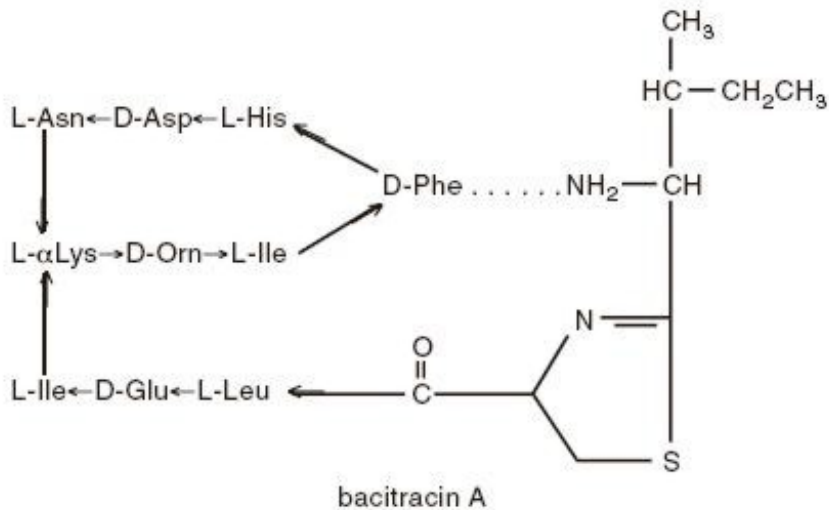
Nephrotoxicity: Bacitracin in parenteral (intramuscular) therapy may cause renal failure due to tubular and glomerular necrosis. Its use should be restricted to infants with staphylococcal pneumonia and empyema when due to organisms shown to be susceptible to bacitracin. It should be used only where 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 should be 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

Sterile Bacitracin, USP is an antibiotic for intramuscular administration. Bacitracin is derived from cultures of *Bacillus subtilis* (Tracey). 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:



The molecular formula is: $C_{66}H_{103}N_{17}O_{16}S$. Bacitracin is comprised of a polypeptide complex and Bacitracin A is the major component in this complex. The molecular weight of Bacitracin A is 1422.71.

CLINICAL PHARMACOLOGY

Bacitracin 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.

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.

Susceptibility Testing

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: <https://www.fda.gov/STIC>.

INDICATIONS AND USAGE

In accordance 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.

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 or prevent 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 and PRECAUTIONS

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

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

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.

Prescribing Bacitracin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

There have been reports of anaphylaxis and/or allergic contact dermatitis in patients exposed to Bacitracin in non-approved indications.

Information for Patients

Patients should be counseled that antibacterial drugs, including Bacitracin, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Bacitracin is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Bacitracin or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

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 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 or 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

Sterile Bacitracin, USP is available in a vial (1's) containing 50,000 units (NDC 0009-0233-01) and as a pack of ten vials (10's) each containing 50,000 units (NDC 0009-0233-03).

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

Rx only

LAB-0026-6.0

04/2018

PRINCIPAL DISPLAY PANEL - 50,000 Unit Vial Label

NDC 0009-0233-01

One Vial

**Bacitracin for
Injection, USP**

50,000 Units

For Intramuscular Use

Rx only

Distributed by Pharmacia & Upjohn Co
Division of Pfizer Inc, NY, NY 10017

Pfizer Injectables

IMPRINT AREA

LOT/EXP
PAA093786

N 0 03 0009-0233-01-3
FPO - RSS 10 Ml

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

DOSAGE AND USE:
See accompanying prescribing information.

Reconstitution with 9.8 mL of sodium chloride injection containing 2 percent procaine hydrochloride will result in a concentration of 5,000 units per mL. Diluents containing parabens should not be used.

Lyophilized in container.
Store solution in a refrigerator 2° to 8°C (36° to 46°F). Discard after 1 week.
Each vial contains 50,000 units Bacitracin.
Reconstituted _____

NDC 0009-0233-01

One Vial
**Bacitracin for
Injection, USP**
50,000 Units
For Intramuscular Use
Rx only

Distributed by Pharmacia & Upjohn Co
Division of Pfizer Inc, NY, NY 10017

Pfizer Injectables

PRINCIPAL DISPLAY PANEL - 50,000 Unit Vial Carton

NDC 0009-0233-01

Rx only

One Vial

**Bacitracin for
Injection, USP**

50,000 Units

For Intramuscular Use

Pfizer Injectables



Bacitracin for Injection, USP
50,000 Units
One Vial
GTIN: 00909090233013

NO VARNISH
NO COPY
NO INK

PAA072313

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

DOSAGE AND USE:

See accompanying prescribing information.

Reconstitution with 9.8 mL of sodium chloride injection containing 2 percent procaine hydrochloride will result in a concentration of 5,000 units per mL. Diluents containing parabens should not be used.

Lyophilized in container.

Store solution in a refrigerator 2° to 8°C (36° to 46°F).

Discard after 1 week.

Each vial contains 50,000 units Bacitracin.

NDC 0009-0233-01
Rx only

One Vial

Bacitracin for Injection, USP
50,000 Units

For Intramuscular Use



Distributed by
Pharmacia & Upjohn Co
Division of Pfizer Inc
NY, NY 10017

One Vial

Bacitracin for Injection, USP
50,000 Units

For Intramuscular Use

Pfizer *Injectables*

LOT/EXP/SN

IMPRINT AREA
READS THIS WAY
NO VARNISH
NO INK
NO COPY

PRINCIPAL DISPLAY PANEL - 10 Vial Carton

NDC 0009-0233-03

Contains 10 of NDC 0009-0233-01

10 Vials

Rx only

Bacitracin for Injection, USP

50,000 Units

For Intramuscular Use

Pfizer Injectables

10 Vials

ND C0009-0233-03
Contains 10 of ND C0009-0233-01

Rx only

Bacitracin for Injection, USP 50,000 Units

For Intramuscular Use

Pfizer *Injectables*



Distributed by
Pharmacia & Upjohn Co
Division of Pfizer Inc
NY, NY 10017

IMPRI NT AREA
NO VARNISH
NO COPY
NO INK

GTIN: 00300090233037
LOT / EXP / SN

10 Vials
Bacitracin for Injection, USP
50,000 Units

PAA072311

10 Vials

Bacitracin for Injection, USP 50,000 Units

Store unrec onstitute d product in a
refrigerator 2° to 8°C (36° to 46°F).

DO SAGE AND USE:

See accompanying prescribing information.

Reconstitution with 9.8 mL of sodium
chloride injection containing 2 percent
procaine hydrochloride will result in a
concentration of 5,000 units per mL.

Diluents containing parabens should not be

For Intramuscular Use

Pfizer *Injectables*



used.
Lyophilized in container.
Store solution in a refrigerator 2° to 8°C
(36° to 46°F).
Discard after 1 week.
Each vial contains 50,000 units Bacitracin.

BACITRACIN

bacitracin injection, powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0009-0233
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN A (UNII: DDA3RRX0P7) (BACITRACIN A - UNII:DDA3RRX0P7)	BACITRACIN A	5000 [USP'U] in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0009-0233-01	1 in 1 CARTON	07/29/1948	01/31/2022
1		10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0009-0233-03	10 in 1 CARTON	07/29/1948	01/31/2022
2		10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA060733	07/29/1948	01/31/2022

Labeler - Pharmacia and Upjohn Company (618054084)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	ANALYSIS(0009-0233) , MANUFACTURE(0009-0233) , PACK(0009-0233) , LABEL(0009-0233)

Revised: 4/2021

Pharmacia and Upjohn Company