BACITRACIN- bacitracin injection, powder, for solution
Civica, Inc.

Bacitracin for Injection, USP

Rx Only

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

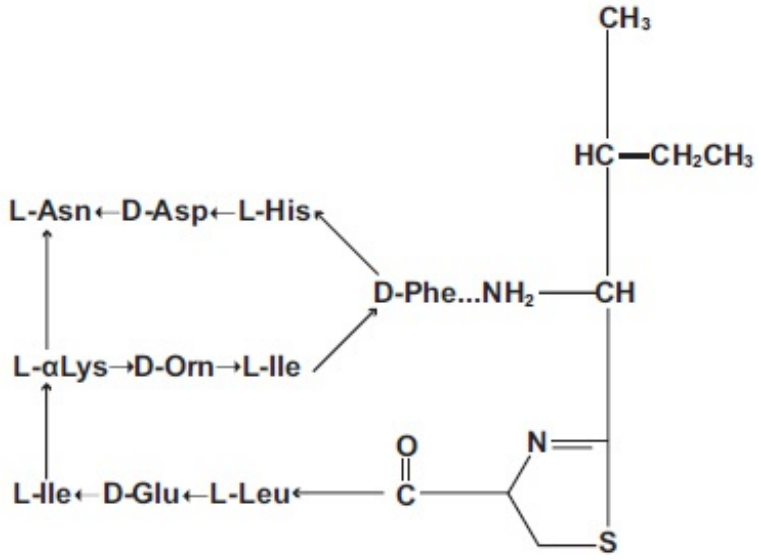
Bacitracin in parenteral (intramuscular) therapy may cause renal failure due to tubular and glomerular necrosis. Its use should be restricted to infants with staphylococcal pneumonia and empyema when due to organisms shown to be susceptible to bacitracin. It should be used only where adequate laboratory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



bacitracin A

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 criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: 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.

PRECAUTIONS

See "Warning Box" 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 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.

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.

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.

To report SUSPECTED ADVERSE REACTIONS, contact Xellia Pharmaceuticals USA, LLC at safety@xellia.com or 1-855-642-2594, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 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.

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 as a pack of ten (10's) with each vial containing 50,000 units (NDC 72572-025-10).

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

Rx Only

Distd by: Civica, Inc., Lehi, Utah 84043

Mfd for: Xellia Pharmaceuticals USA, LLC
Made in Hyderabad, Telangana India

LEA-020307-00

Revised: October 2019

PRINCIPAL DISPLAY PANEL - 10 Vial Carton

NDC - 72572-025-10
Rx Only

Bacitracin for Injection, USP

50,000 units per vial

CIVICA™

For Intramuscular Use

10 vials

153 x 62 x 75 mm

NDC - 72572-**025**-10 Rx Only

Bacitracin for Injection, USP

50,000 units per vial

CIVICA™

For Intramuscular Use

10 vials

(01)30372572025103

Code No.: AP/DRUGS/103/97

Varnish free area
(min. 153x62 mm)

GTIN: 30372572025103

CAR-009973-00

Each vial contains 50,000 units Bacitracin.

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.

Store solution in a refrigerator 2° to 8°C (36° to 46°F). Discard after 1 week.

Lyophilized in container.

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NDC - 72572-**025**-10 Rx Only

Bacitracin for Injection, USP

50,000 units per vial

For Intramuscular Use

CIVICA™

BACITRACIN

bacitracin injection, powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72572-025
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Bacitracin (UNII: 58H6RWO52I) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	50000 [USP'U]

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72572-025-10	10 in 1 CARTON	12/01/2019	
1	NDC:72572-025-01	1 in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203177	12/01/2019	

Labeler - Civica, Inc. (081373942)

Registrant - Xellia Pharmaceuticals ApS (305814345)

Revised: 12/2020 Civica, Inc.