

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 (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:

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

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 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 feel you have been administered too much Bacitracin (injection), contact your attending healthcare professional.

In case of drug overdose with the 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 call your doctor or pharmacist |
|------------------|--|-------------------------------------|--------------|---|
| | | 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) | | √ | √ |

health professionals can be found at: <http://www.Pfizer.ca> or by contacting Pfizer Canada Inc. Medical Information at 1-800-463-6001.

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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 unconstituted 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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for