#### 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 <u>only</u> 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
		Only if severe	In all cases	immediate medical help
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.)		7	√
	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
   (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>) 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 (<a href="https://health-products.canada.ca/dpd-bdpp/index-eng.jsp">https://health-products.canada.ca/dpd-bdpp/index-eng.jsp</a>); the manufacturer's website (<a href="www.pfizer.ca">www.pfizer.ca</a>), or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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