

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PRIMAXIN®

imipenem and cilastatin sodium for injection

Read this carefully before you start taking PRIMAXIN® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about PRIMAXIN®.

Serious Warnings and Precautions

- **Serious allergic reactions sometimes causing death have happened in patients taking similar medicines like PRIMAXIN® and can also occur with PRIMAXIN®.**
- **Before starting therapy with PRIMAXIN®, tell your doctor about any allergic reactions you have had in the past to other antibiotics or to any other medicines.**
- **If an allergic reaction to PRIMAXIN® occurs, stop taking the medicine and consult your doctor right away. See Serious side effects and what to do about them, below.**

What is PRIMAXIN® used for?

Your physician has prescribed PRIMAXIN® to treat one of the following infections:

- Lung Infections.
- Infections of your urinary tract.
- Infections of your abdomen.
- Infections of the female reproductive system.
- Infection of your blood.
- Infection of your heart called endocarditis caused by a bacterial strain called *Staphylococcus aureus*.
- Infections of your bones and joints.
- Skin Infections.

Antibacterial drugs like PRIMAXIN® treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, PRIMAXIN® should be used exactly as directed. Misuse or overuse of PRIMAXIN® could lead to the growth of bacteria that will not be killed by PRIMAXIN® (resistance). This means that PRIMAXIN® may not work for you in the future.

How does PRIMAXIN® work?

PRIMAXIN® is an antibiotic. It is used to kill a wide range of bacteria that cause infections.

What are the ingredients in PRIMAXIN®?

Medicinal ingredients: imipenem and cilastatin sodium.

Non-medicinal ingredients: sodium bicarbonate.

PRIMAXIN® comes in the following dosage forms:

Sterile powder for solution, 500 mg imipenem and 500 mg cilastatin (as cilastatin sodium) per vial

Do not use PRIMAXIN® if:

- You or your child are allergic to any of its ingredients (see **What are the ingredients in PRIMAXIN®**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRIMAXIN®. Talk about any health conditions or problems you may have, including if you:

- allergies to any drugs, including beta-lactam antibiotics such as penicillins, or cephalosporins or any other class of antibiotics.
- colitis or any other gastrointestinal (stomach or bowel) disease.
- any central nervous system disorders, such as localized tremors, brain lesions or seizures.
- kidney or urinary problems.

Other warnings you should know about:

Use in Pregnancy and Breast-feeding

Use in Pregnancy

PRIMAXIN® is not generally recommended in pregnant women. You should tell your doctor if you think you are pregnant or plan to become pregnant.

Use in Breast-feeding

PRIMAXIN® is secreted in human milk. As the breast-fed baby may be affected, women who are receiving PRIMAXIN® should not breast-feed. If you intend to breast-feed, talk to your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PRIMAXIN®:

- ganciclovir - used to treat some viral infections.
- valproic acid - used to treat epilepsy, bipolar disorder, migraine, or schizophrenia.

Your doctor will decide whether you should use PRIMAXIN® in combination with these medicines.

How to take PRIMAXIN®:

- PRIMAXIN® will be injected into a vein (intravenous injection). PRIMAXIN® must not be taken by mouth.

Usual dose:

PRIMAXIN® will be given to you by a physician or another health care professional who will determine the most appropriate method and dose. The number, type of injection and amount in each injection that you require will depend upon your condition, the severity of your infection as well as the overall health of your kidneys.

It is very important that you continue to receive PRIMAXIN® for as long as your doctor prescribes it.

Your doctor will let you know when you may stop receiving PRIMAXIN®.

Overdose:

If you think you, or a person you are caring for, have taken too much PRIMAXIN®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

The injection schedule will be set by your doctor, who will monitor your response and condition to determine what treatment is needed. However, if you are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

What are possible side effects from using PRIMAXIN®?

These are not all the possible side effects you or your child may have when taking PRIMAXIN®. If you or your child experience any side effects not listed here, tell your healthcare professional.

Common side effects of PRIMAXIN®:

- nausea
- vomiting
- skin redness and tenderness at the injection site or along a blood vessel in the area

Uncommon side effects of PRIMAXIN®:

- hives
- rash
- skin itchiness
- fever
- dizziness
- sleepiness
- low blood pressure

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Children			
COMMON			
diarrhea		✓	
Adults			
UNCOMMON			
seizures			✓
<i>Clostridium colitis</i> (inflammation of the colon caused by a bacteria) <i>Clostridium</i>)			✓
Adults or children			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<p>UNCOMMON Serious hypersensitivity and allergic reactions, occasionally fatal, with symptoms such as severe rash with or without high fever, with itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing</p>			✓
<p>UNKNOWN Severe Cutaneous Adverse Reactions (SCAR): severe skin reactions that may also affect other organs:</p> <ul style="list-style-type: none"> • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough • Shortness of breath, chest pain or discomfort 			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.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.

Storage:

Store the dry powder at room temperature between 15-30°C.

Keep out of reach and sight of children.

If you want more information about PRIMAXIN®:

- 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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