

PRIMAXIN®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given PRIMAXIN?

PRIMAXIN contains the active ingredients Imipenem and Cilastatin sodium. PRIMAXIN is an antibiotic which is used to treat serious infections caused by bacteria. These infections may occur in many different parts of the body.

For more information, see Section [1. Why am I being given PRIMAXIN?](#) in the full CMI.

2. What should I know before I am given PRIMAXIN?

Do not use if you have ever had an allergic reaction to PRIMAXIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given PRIMAXIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRIMAXIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given PRIMAXIN?

- PRIMAXIN will be prepared and given to you by a doctor or nurse. It is given as a slow injection into a vein.
- Your doctor will decide what dose of PRIMAXIN you will receive, depending upon your condition and the severity of your infection.
- PRIMAXIN is usually given in divided doses throughout the day.

More instructions can be found in Section [4. How am I given PRIMAXIN?](#) in the full CMI.

5. What should I know while being given PRIMAXIN?

Things you should do	<p>Tell your doctor if:</p> <ul style="list-style-type: none">• If you feel sick while you are receiving PRIMAXIN.• If you develop severe diarrhoea, even if it occurs several weeks after PRIMAXIN has been stopped.• If you develop a severe skin reaction such as painful red areas, fluid-filled bumps, large blisters, or peeling of layers of skin whilst being given PRIMAXIN• If you have a history of seizures and you are taking anticonvulsant medicines
Driving or using machines	<ul style="list-style-type: none">• PRIMAXIN generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause dizziness or

	lightheadedness in some people. Make sure you know how you react to PRIMAXIN before you drive a car or operating machinery.
Looking after your medicine	<ul style="list-style-type: none"> ● PRIMAXIN will be stored in the pharmacy or on the ward. ● The powder for injection is kept in a cool dry place where the temperature stays below 25°C

For more information, see Section [5. What should I know while being given PRIMAXIN?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or nurse if you notice any of the following and they worry you: pain, swelling or red skin where you had the injection, nausea, vomiting, diarrhoea. These are the more common side effects of PRIMAXIN.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PRIMAXIN

Active ingredients: *Imipenem and Cilastatin sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about PRIMAXIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about PRIMAXIN.**

Where to find information in this leaflet:

- [1. Why am I being given PRIMAXIN?](#)
- [2. What should I know before I am given PRIMAXIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given PRIMAXIN?](#)
- [5. What should I know while being given PRIMAXIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given PRIMAXIN?

PRIMAXIN contains the active ingredients Imipenem and Cilastatin sodium. PRIMAXIN is an antibiotic which is used to treat serious infections caused by bacteria. These infections may occur in many different parts of the body.

PRIMAXIN is sometimes given in addition to other antibiotics.

PRIMAXIN works by killing the bacteria causing the infection.

2. What should I know before I am given PRIMAXIN?

Warnings

Do not use PRIMAXIN if:

- you are allergic to PRIMAXIN, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can be given this medicine.

Check with your doctor if you:

- **are pregnant or are breast-feeding**
- **have any medical conditions, especially the following:**
 - colitis or any other gastrointestinal disease
 - any central nervous system disorders, such as localised tremors, or seizures (fits)
 - kidney or urinary problems
 - bowel problems
- **you have any allergies to other antibiotics, in particular, penicillins and cephalosporins**

If you are allergic to any of these, you may be allergic to PRIMAXIN.

- **if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you are given PRIMAXIN.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the possible risks and benefits of being given PRIMAXIN during pregnancy and breastfeeding. PRIMAXIN passes into breast milk and may be passed on to the baby.

Children

PRIMAXIN should not be given to children under 3 months of age or children with kidney problems.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with PRIMAXIN and affect how it works.

Tell your doctor if you are taking:

- Sodium valproate (medicine used to treat epilepsy, bipolar disorder, migraine or schizophrenia)
- Ganciclovir (a medicine used to treat some viral infections)
- Probenecid (a medicine used to treat gout)

Your doctor or pharmacist will be able to tell you what to do when being given PRIMAXIN with other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PRIMAXIN.

4. How am I given PRIMAXIN?

How it is given

PRIMAXIN will be prepared and given to you by a doctor or nurse. It is given as a slow injection into a vein.

Your doctor will decide what dose of PRIMAXIN you will receive, depending upon your condition and the severity of your infection.

PRIMAXIN is usually given in divided doses throughout the day.

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

If you have been given too much PRIMAXIN

If you think that you have been given too much PRIMAXIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given PRIMAXIN?

Things you should do

Call your doctor straight away if you:

- **feel sick while you are receiving PRIMAXIN**

Your doctor may need to slow down the rate of the injection.

- **develop severe diarrhoea, even if it occurs several weeks after PRIMAXIN has been stopped**

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

- **develop a severe skin reaction such as painful red areas, fluid-filled bumps, large blisters, or peeling of layers of skin whilst being given PRIMAXIN**

You may need urgent medical care.

- **have a history of seizures and you are taking anticonvulsant medicines**

You should continue taking these medicines unless your doctor tells you otherwise. Some patients may develop tremors or seizures while receiving PRIMAXIN.

Things you should do after having been given PRIMAXIN

Tell your doctor immediately if you notice any of the following side effects particularly if they occur several weeks after you have been given treatment with PRIMAXIN:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody

- fever

These are all serious side effects. You may have a serious condition affecting your bowel. You may need urgent medical attention. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PRIMAXIN affects you.

PRIMAXIN generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause dizziness or lightheadedness in some people. Make sure you know how you react to PRIMAXIN before you drive a car or operating machinery.

Looking after your medicine

- PRIMAXIN will be stored in the pharmacy or on the ward.
- The powder for injection is kept in a cool dry place where the temperature stays below 25°C.

6. Are there any side effects?

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given PRIMAXIN.

PRIMAXIN helps most people with infection, but it may have unwanted side-effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. PRIMAXIN generally does not cause any problems.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<p>Tell your doctor or nurse if you notice any of the following and they worry you:</p> <ul style="list-style-type: none"> ● pain, swelling or red skin where you had the injection ● nausea, vomiting ● diarrhoea <p>These are the more common side effects of PRIMAXIN.</p>	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Tell your doctor or nurse immediately if you notice any of the following:</p> <ul style="list-style-type: none">• high temperature, also called fever• seizures or fits• tremors, confusion• abnormal movements• agitation• tingling or numbness of the hands and feet• fast or irregular heart beat, also called palpitations• passing little or no urine (water)• bruising more easily than normal• signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers• signs of anaemia, such as tiredness, being short	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>of breath, and looking pale</p> <ul style="list-style-type: none"> ● yellowing of the skin and eyes, also called jaundice ● skin problems such as rash or itchiness ● red or purplish-red patches on the skin ● severe skin reactions, such as painful red areas, fluid-filled bumps, large blisters, or peeling of layers of skin have been reported for the beta-lactam class of antibiotics ● hearing loss ● severe abdominal or stomach cramps ● watery and severe diarrhoea, which may also be bloody <p>These are serious side effects of PRIMAXIN. You may need urgent medical attention. Serious side effects are rare.</p>	

Allergic Reactions

Allergic Reactions	What to do
<p>A few people may be allergic to some medicines. Tell your doctor or nurse immediately if you notice any of the following:</p> <ul style="list-style-type: none">• dizziness, lightheadedness, fainting• swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing• shortness of breath• itchy skin rash• pinkish, itchy swellings on the skin, also called hives or nettlerash <p>If you have these, you may have had a serious allergic reaction to PRIMAXIN. You may need urgent medical attention.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these Allergic Reactions.</p>

Also, tell your doctor if you notice:

- staining of the teeth and/or tongue
- a change in the colour of your urine

These are other side effects that have been reported with PRIMAXIN.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PRIMAXIN contains

Active ingredient (main ingredient)	Imipenem 500 mg and cilastatin 500 mg (as the sodium salt) per vial
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Other ingredients (inactive ingredients)	sodium bicarbonate
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Do not take this medicine if you are allergic to any of these ingredients.

What PRIMAXIN looks like

Solutions of PRIMAXIN range from colourless to yellow.

Australian Registration Number:

PRIMAXIN - AUST R 10509

Who distributes PRIMAXIN

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113 Australia

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