

Package leaflet: Information for the user

PRIMAXIN® IV 500mg /500mg Powder for Solution for Infusion

imipenem/cilastatin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet:

1. What PRIMAXIN IV is and what it is used for
2. What you need to know before you use PRIMAXIN IV
3. How to use PRIMAXIN IV
4. Possible side effects
5. How to store PRIMAXIN IV
6. Contents of the pack and other information

1. What PRIMAXIN IV is and what it is used for

PRIMAXIN IV belongs to a group of medicines called carbapenem antibiotics. It kills a wide range of bacteria (germs) that cause infections in various parts of the body in adults and children one year of age and above.

Treatment

Your doctor has prescribed PRIMAXIN IV because you have one (or more) of the following types of infection:

- Complicated infections in the abdomen
- Infection affecting the lungs (pneumonia)
- Infections that you can catch during or after the delivery of your baby
- Complicated urinary tract infections
- Complicated skin and soft tissue infections

PRIMAXIN IV may be used in the management of patients with low white blood cell counts, who have fever that is suspected to be due to a bacterial infection.

PRIMAXIN IV may be used to treat bacterial infection of the blood which might be associated with a type of infection mentioned above.

2. What you need to know before you use PRIMAXIN IV

Do not use PRIMAXIN IV

- if you are allergic to imipenem, cilastatin or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other antibiotics such as penicillins, cephalosporins, or carbapenems

Warnings and Precautions

Tell your doctor about any medical condition you have or have had including:

- allergies to any medicines including antibiotics (sudden life-threatening allergic reactions require immediate medical treatment)
- colitis or any other gastrointestinal disease
- kidney or urinary problems, including reduced kidney function (PRIMAXIN IV blood levels increase in patients with reduced kidney function. Central nervous system adverse reactions may occur if the dose is not adjusted to the kidney function)
- any central nervous system disorders such as localized tremors or epileptic seizures (fits)
- liver problems

You may develop a positive test (Coombs test) which indicates the presence of antibodies that may destroy red blood cells. Your doctor will discuss this with you.

Children

PRIMAXIN IV is not recommended in children less than one year of age or children with kidney problems.

Other medicines and PRIMAXIN IV

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking ganciclovir which is used to treat some viral infections.

Also, tell your doctor if you are taking valproic acid or sodium valproate (used to treat epilepsy, bipolar disorder, migraine, or schizophrenia) or any blood thinners such as warfarin.

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

Pregnancy and breast-feeding

It is important that you tell your doctor if you are pregnant or are planning to become pregnant before receiving PRIMAXIN IV. PRIMAXIN IV has not been studied in pregnant women. PRIMAXIN IV should not be used during pregnancy unless your doctor decides the potential benefit justifies the potential risk to the developing baby.

It is important that you tell your doctor if you are breast-feeding or if you intend to breast-feed before receiving PRIMAXIN IV. Small amounts of this medicine may pass into breast milk and it may affect the baby. Therefore, your doctor will decide whether you should use PRIMAXIN IV while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There are some side effects associated with this product (such as seeing, hearing, or feeling something that is not there, dizziness, sleepiness, and a spinning sensation) that may affect some patients' ability to drive or operate machinery (see section 4).

PRIMAXIN IV contains sodium

This medicinal product contains approximately 1.6 mEq (approximately 37.6 mg) of sodium per 500 mg dose which should be taken into consideration by patients on a controlled sodium diet.

3. How to use PRIMAXIN IV

PRIMAXIN IV will be prepared and given to you by a doctor or another health care professional. Your doctor will decide how much PRIMAXIN IV you need.

Use in adults and adolescents

The recommended dose for adults and adolescents is 500 mg/500 mg every 6 hours or 1,000 mg/1,000 mg every 6 or 8 hours. If you have kidney problems your doctor may lower your dose.

Use in children

The recommended dose for children one year of age or older is 15/15 or 25/25 mg/kg/dose every 6 hours. PRIMAXIN IV is not recommended in children under one year of age and children with kidney problems.

Method of administration

PRIMAXIN IV is given intravenously (into a vein) over 20-30 minutes for a dose of ≤ 500 mg/500 mg or 40-60 minutes for a dose of > 500 mg/500 mg. The rate of infusion may be slowed if you feel sick.

If you use more PRIMAXIN IV than you should

Symptoms of overdose may include seizures (fits), confusion, tremors, nausea, vomiting, low blood pressure and slow heart rate. If you are concerned that you may have been given too much PRIMAXIN IV, contact your doctor or another healthcare professional immediately.

If you forget to use PRIMAXIN IV

If you are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000

- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data

The following side-effects occur rarely, however if they do occur, while receiving or after receiving PRIMAXIN IV, the medicine must be stopped and your doctor contacted immediately.

- Allergic reactions including rash, swelling of the face, lips, tongue, and/or throat (with difficulty in breathing or swallowing), and/or low blood pressure
- Skin peeling (toxic epidermal necrolysis)
- Severe skin reactions (Stevens-Johnson syndrome and erythema multiforme)
- Severe skin rash with loss of skin and hair (exfoliative dermatitis)

Other possible side effects:

Common

- Nausea, vomiting, diarrhoea. Nausea and vomiting appear to occur more frequently in patients with low number of white blood cells
- Swelling and redness along a vein which is extremely tender when touched
- Rash
- Abnormal liver function detected by blood tests
- Increase in some white blood cells

Uncommon

- Local skin redness
- Local pain and formation of a firm lump at the injection site
- Skin itchiness
- Hives
- Fever
- Blood disorders affecting the cell components of the blood and usually detected by blood tests (symptoms may be tiredness, paleness of skin, and prolonged bruising after injury)
- Abnormal kidney, liver and blood function detected by blood tests
- Tremors and uncontrolled twitching of muscles
- Seizures (fits)
- Psychic disturbances (such as mood swings and impaired judgment)
- Seeing, hearing or feeling something that is not there (hallucinations)
- Confusion
- Dizziness, sleepiness
- Low blood pressure

Rare

- Fungal infection (candidiasis)
- Staining of the teeth and/or tongue
- Inflammation of the colon with severe diarrhoea
- Disturbances in taste
- Inability of the liver to perform normal function
- Inflammation of the liver
- Inability of the kidney to perform normal function
- Changes in the amount of urine, changes in urine colour
- Disease of the brain, tingling sensation (pins and needles), localised tremor
- Hearing loss

Very rare

- Severe loss of liver function due to inflammation (fulminant hepatitis)
- Inflammation of stomach or intestine (gastro-enteritis)
- Inflammation of intestine with bloody diarrhoea (haemorrhagic colitis)
- Red swollen tongue, overgrowth of the normal projections on the tongue giving it a hairy appearance, heartburn, sore throat, increase in the production of saliva
- Stomach pain
- A spinning sensation (vertigo), headache
- Ringing in the ears (tinnitus)
- Pain in several joints, weakness
- Irregular heartbeat, the heart beating forcefully or rapidly
- Chest discomfort, difficulty breathing, abnormally fast and superficial breathing, pain in the upper spine
- Flushing, bluish discoloration of the face and lips, skin texture changes, excessive sweating
- Itching of the vulva in women
- Changes in the amounts of blood cells
- Worsening of a rare disease associated with muscle weakness (aggravation of myasthenia gravis)

Not known

- Abnormal movements
- Agitation

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

Malta: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5. How to store PRIMAXIN IV

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the container. The expiry date refers to the last day of that month.

Do not store above 25 °C.

After reconstitution:

Diluted solutions should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed two hours.

Do not freeze the reconstituted solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer used. These measures will help protect the environment.

6. Contents of the pack and other information

What PRIMAXIN IV contains

- The active substances are imipenem and cilastatin. Each vial contains imipenem monohydrate equivalent to 500 mg imipenem and cilastatin sodium equivalent to 500 mg cilastatin.
- The other ingredient is sodium bicarbonate.

What PRIMAXIN IV looks like and contents of the pack

PRIMAXIN IV is a white to light yellow powder for solution for infusion in a glass vial. Pack sizes of 1, 10 or 25 vials. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

The Marketing Authorisation Holder in the UK and Malta is Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK. The Marketing Authorisation Holder in Ireland is Merck Sharp & Dohme Ireland (Human Health) Ltd, Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland.

The manufacturer is Merck Sharp and Dohme –Chibret, Mirabel Plant, Route de Marsat, Cedex 9, Riom, France.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Zienam
Belgium: Tienam
Bulgaria: Tienam
Cyprus: Tienam
Czech Republic: Tienam
Estonia: TIENAM I.V.
Finland: TIENAM
France: TIENAM
Germany: ZIENAM
Greece: Primaxin
Hungary: Tienam
Ireland: Primaxin IV
Italy: TIENAM (20 ml)
Latvia: TIENAM I.V.
Lithuania: TIENAM I.V.
Luxembourg: Tienam
Malta: Primaxin IV
Netherlands: TIENAM
Norway: Tienam
Poland: TIENAM
Portugal: Tienam IV
Slovenia: Tienam
Spain: TIENAM
Sweden: Tienam
United Kingdom: Primaxin IV

This leaflet was last revised in December 2017

The following information is intended for medical or healthcare professionals only:

Each vial is for single use only.

Reconstitution

Contents of each vial must be transferred to 100 ml of an appropriate infusion solution (see **Incompatibility** and **After reconstitution**): 0.9% sodium chloride. In exceptional circumstances where 0.9% sodium chloride cannot be used for clinical reasons, 5% glucose may be used instead.

A suggested procedure is to add approximately 10 ml of the appropriate infusion solution to the vial. Shake well and transfer the resulting mixture to the infusion solution container.

CAUTION: THE MIXTURE IS NOT FOR DIRECT INFUSION.

Repeat with an additional 10 ml of infusion solution to ensure complete transfer of vial contents to the infusion solution. The resulting mixture should be agitated until clear.

The concentration of the reconstituted solution following the above procedure is approximately 5 mg/ml for both imipenem and cilastatin.

Variations of colour, from colourless to yellow, do not affect the potency of the product.

Incompatibility

This medicinal product is chemically incompatible with lactate and should not be reconstituted in diluents containing lactate. However, it can be administered into an I.V. system through which a lactate solution is being infused.

This medicinal product must not be mixed with other medicinal products except those mentioned under **Reconstitution**.

After reconstitution

Diluted solutions should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed two hours.

Any unused product or waste material should be disposed of in accordance with local requirements.

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