

I m i p e n e m / C i l a s t a t i n 5 0 0 m g / 5 0 0 m g Powder for Solution for Infusion

What is this leaflet

• The full name of this product is Imipenem/Cilastatin
• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
• The full name of this product is Imipenem/Cilastatin 500mg/500mg Powder for Solution for Infusion but within the leaflet it will be referred to as Imipenem/Cilastatin powder.

What is in this leaflet:

1. What Imipenem/Cilastatin powder is and what it is used for
2. What you need to know before you use
   a. How to use
   b. Possible side effects
   c. How to store
   d. Contents of the pack and other information

Imipenem/Cilastatin powder 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. Imipenem/Cilastatin powder may be used to treat bacterial infection of the blood which might be associated with a type of infection mentioned above.

What you need to know before you use

Do not use Imipenem/Cilastatin powder if you are allergic to imipenem, cilastatin or any of the other ingredients of this medicine (listed in section 6).

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
• any central nervous system disorders such as localized tremors or epileptic seizures
• liver, kidney or urinary problems

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

Tell your doctor if you are taking medicines called valproic acid or sodium valproate (see Other medicines and Imipenem/Cilastatin below).

Children

Imipenem/Cilastatin powder is not recommended in children less than one year of age or children with kidney problems.

Using other medicines

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.

Tell your doctor if you are taking medicines called valproic acid or sodium valproate (used to treat epilepsy, bipolar disorder, migraine, or schizoaffective disorders) or any blood thinners such as warfarin.

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).

What Imipenem/Cilastatin powder contains sodium

This medicinal product contains 1.6 mmol (or 37.6mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

How to store

Keep the bottle of powder in the refrigerator. The vials must be discarded if not used within 14 days of opening. Keep the bottle tightly closed.

How to use

Reconstitution of Imipenem/Cilastatin powder

1. Black colours/plates:

<table>
<thead>
<tr>
<th>Strength</th>
<th>Recommended volume of diluent added (ml)</th>
<th>Approximate concentration of imipenem (mg/ml)</th>
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<tbody>
<tr>
<td>Imipenem/ Cilastatin powder 500 mg</td>
<td>100</td>
<td>5</td>
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The following information is intended for healthcare professionals only:

Preparation of intravenous solution

The following table is provided for convenience in reconstituting Imipenem/Cilastatin powder for intravenous infusion.

Imipenem/Cilastatin all strengths powder for solution 1 vial packs PIL UK

Your doctor will decide whether you should use Imipenem/Cilastatin powder in combination with these medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Imipenem/Cilastatin powder has not been studied in pregnant women. Imipenem/Cilastatin powder should not be used during pregnancy unless your doctor decides the potential benefit justifies the potential risk to the foetus.

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 Imipenem/Cilastatin powder while breast-feeding.

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

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Imipenem/Cilastatin powder will be prepared and given to you by a doctor or another health care professional. Your doctor will decide how much Imipenem/Cilastatin powder you need.

Children
The usual dose for children one year of age or older is 5-15 mg/kg body weight every 6 hours. Imipenem/Cilastatin powder is not recommended in children under one year of age and children with kidney problems.

Method of administration
Imipenem/Cilastatin powder 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/300 mg. If you use more Imipenem/Cilastatin powder than you should
Symptoms of overdose may include seizures, confusion, tremors, nausea, vomiting, low blood pressure and slow heart rate. If you are concerned that you may have taken too much Imipenem/Cilastatin powder, contact your doctor or another healthcare professional immediately.

If you forget to use Imipenem/Cilastatin powder
If you are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately. Do not take a double dose to make up for a forgotten dose.

If you stop using Imipenem/Cilastatin powder
Do not stop using Imipenem/Cilastatin powder until your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects
Like all medicines, Imipenem/Cilastatin powder can cause side-effects in some people—everybody gets them.

Common (may affect up to 1 in 10 people):
- Nausea, vomiting, diarrhoea
- 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 (may affect up to 1 in 100 people):
- Local skin redness
- Local pain and formation of a lump at the injection site
- Skin itching
- Fever
- Blood disorders affecting the cell components of the blood and usually detected by blood tests (symptoms may include tiredness, paleness of skin, and prolonged bruising after injury)
- Abnormal kidney, liver and blood function detected by blood tests

Rare (may affect up to 1 in 1,000 people):
- Allergic reactions including rash, swelling of the face, lips, tongue and/or throat with difficulty in breathing or swallowing, and/or low blood pressure
- Fungal infection (candidiasis)
- Skin peeling (lattice epidermal necrolysis)
- Severe reactions (Stevens-Johnson syndrome and erythema multiforme)
- Severe skin rash with loss of skin and hair (exfoliative dermatitis)
- 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 (may affect up to 1 in 10,000 people):
- Severe loss of liver function due to inflammation (luminant 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 forcibly 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)

This leaflet was last revised in November 2015

If you would like a leaflet with larger text, please contact 01271 311257.