

IMIPENEM+CILASTATIN RBX®

imipenem/cilastatin sodium

500 mg/500 mg Powder for Solution for Infusion

What is in this leaflet

This leaflet answers some common questions about IMIPENEM+CILASTATIN RBX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you using IMIPENEM+CILASTATIN RBX against the benefits he or she expects it will have for you. If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What IMIPENEM+CILASTATIN RBX is used for

IMIPENEM+CILASTATIN RBX is an antibiotic which is used to treat serious infections caused by bacteria (germs). These infections may occur in many different parts of the body. IMIPENEM+CILASTATIN RBX is sometimes given in addition to other antibiotics. IMIPENEM+CILASTATIN RBX works by killing the bacteria causing the infection.

Before you are given IMIPENEM+CILASTATIN RBX

When you must not be given it

Do not use IMIPENEM+CILASTATIN RBX if you have an allergy to the active ingredients imipenem/cilastatin sodium or any of the ingredients listed at the end of this leaflet.

Before you are given it

Your doctor must know about all of the following before you are given IMIPENEM+CILASTATIN RBX, if you have or have had:

- any allergies to other antibiotics, in particular, penicillins and cephalosporins
- allergies to any other substances, such as foods, preservatives, or dyes If you have any of these allergies you may be allergic to IMIPENEM+CILASTATIN RBX.
- a history of seizures or fits, or brain disease
- kidney disease or urinary problems
- any other medical conditions, including problems with your bowels

Tell your doctor if you are taking a medicine containing valproic acid. If you are pregnant or are breast-feeding your doctor will discuss the possible risks and benefits of using IMIPENEM+CILASTATIN RBX during pregnancy and breast-feeding. IMIPENEM+CILASTATIN RBX passes into breast milk. Some medicines may affect the way other medicines work, and some should not be used together at all as they may harm people. If you have not told your doctor about any of the above, tell them before you are given any IMIPENEM+CILASTATIN RBX.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Tell your doctor if you are taking ganciclovir which is used to treat some viral infections. Also, tell your doctor if you are taking a medicine containing valproic acid (used to treat epilepsy, bipolar disorder, migraine, or schizophrenia). Your doctor will decide whether you should use IMIPENEM+CILASTATIN RBX in combination with these medicines.

How IMIPENEM+CILASTATIN RBX is given

IMIPENEM+CILASTATIN RBX is given as a slow injection into a vein. IMIPENEM+CILASTATIN RBX must only be given by a doctor or nurse. Your doctor will decide what dose of IMIPENEM+CILASTATIN RBX you will receive, depending on your infection and other factors, such as your weight. IMIPENEM+CILASTATIN RBX is usually given in divided doses throughout the day.

While you are using IMIPENEM+CILASTATIN RBX

Things you must do

- Tell your doctor, pharmacist or nurse if you feel sick while you are receiving IMIPENEM+CILASTATIN RBX. Your doctor may need to slow down the rate of the injection.
- Tell your doctor, pharmacist or nurse if you develop severe diarrhoea, even if it occurs several weeks after IMIPENEM+CILASTATIN RBX 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 diarrhoea medicine without first checking with your doctor.
- Tell your doctor if you 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 IMIPENEM+CILASTATIN RBX.

Things to be careful of

Be careful driving or operating machinery until you know how IMIPENEM+CILASTATIN RBX affects you. IMIPENEM+CILASTATIN RBX generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause dizziness or light-headedness in some people. Make sure you know how you react to IMIPENEM+CILASTATIN RBX before you drive a car or operate machinery.

Adverse Effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are being given IMIPENEM+CILASTATIN RBX. IMIPENEM+CILASTATIN RBX helps most people with infection, but it may have unwanted adverse-effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. IMIPENEM+CILASTATIN RBX generally does not cause any problems.

Ask your doctor or pharmacist to answer any questions you may have.

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 adverse effects of IMIPENEM+CILASTATIN RBX.

Tell your doctor or nurse immediately if you notice any of the following:

- high temperature or fever
- seizures or fits
- tremors, confusion
- encephalopathy
- mood swings and/or impaired judgement
- hallucinations
- tingling or numbness of the hands and feet
- fast or irregular heart beat, also called palpitations
- passing little or no urine
- 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 of breath, and looking pale
- yellowing of the skin and eyes, also called jaundice
- signs of liver disease, also called hepatitis
- skin problems such as rash or itchiness
- red or purplish-red patches on the skin
- hearing loss
- taste distortion
- severe abdominal or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- tongue discolouration
- fever caused by the medicine

These are serious adverse effects of IMIPENEM+CILASTATIN RBX. You may need urgent medical attention. Serious adverse effects are rare.

A few people may be allergic to some medicines. Tell your doctor or nurse immediately if you notice any of the following:

- dizziness, light-headedness, 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

If you have these, you may have had a serious allergic reaction to IMIPENEM+CILASTATIN RBX. You may need urgent medical attention.

Also, tell your doctor if you notice:

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

These are other adverse effects that have been reported with IMIPENEM+CILASTATIN RBX.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After IMIPENEM+CILASTATIN RBX has been stopped**Things you must do**

Tell your doctor immediately if you notice any of the following adverse effects particularly if they occur several weeks after stopping treatment with IMIPENEM+CILASTATIN RBX:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea,
- blood in stool
- fever

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

Storage

IMIPENEM+CILASTATIN RBX will be stored in the pharmacy or on the hospital ward. The powder for injection is kept in a cool dry place where the temperature stays below 25°C. Do not use IMIPENEM+CILASTATIN RBX if the expiry date printed on the pack has passed.

Product description**Ingredients*****Active ingredients:***

IMIPENEM+CILASTATIN RBX 500 - imipenem 500 mg and cilastatin 500 mg (as the sodium salt) per vial

Inactive ingredients: sodium bicarbonate

Supplier

Douglas Pharmaceuticals Ltd
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