

PATIENT INFORMATION LEAFLET**SEPENCIL RANGE****SCHEDULING STATUS****S4****PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:****SEPENCIL 250 mg** Powder for solution for infusion**SEPENCIL 500 mg** Powder for solution for infusion**Read all of this leaflet carefully before you are given SEPENCIL injection**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **SEPENCIL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT SEPENCIL CONTAINS Active ingredients:

SEPENCIL 250 mg: Each vial contains imipenem monohydrate equivalent to 250 mg imipenem and cilastatin sodium equivalent to 250 mg cilastatin.

SEPENCIL 500 mg: Each vial contains imipenem monohydrate equivalent to 500 mg imipenem and cilastatin sodium equivalent to 500 mg cilastatin.

2. WHAT SEPENCIL IS USED FOR

SEPENCIL belongs to the antibiotic group of medicines known as the carbapenems.

SEPENCIL is used for a variety of bacterial infections caused by organisms susceptible to

SEPENCIL. These include abdominal infections, certain lower respiratory tract infections, gynaecological infections, infection of the blood, urinary tract infections, skin and soft tissue

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infections, bone and joint infections. It is also used preventatively prior to certain surgical procedures.

3. BEFORE YOU ARE ADMINISTERED SEPENCIL INJECTION:***You should not be administered SEPENCIL:***

- If you are hypersensitive (allergic) to imipenem or cilastatin
- If you are pregnant, are planning to become pregnant, or are breastfeeding (see Pregnancy and Breastfeeding)
- If you have meningitis.

Tell your doctor or healthcare professional before being given the injection if:

- If you are generally allergic. Please tell your doctor about all allergic reactions you have had previously, especially to medicines.
- If you are allergic to penicillin, cephalosporin or carbapenem antibiotics, as you may have an increased chance of being allergic to **SEPENCIL** as well.
- If you have meningitis (an alternate antibiotic should be used)
- If you have any nervous system disorder, such as seizures.
- If you have a kidney disorder.

If you have a history of stomach disorders (like diarrhoea), are currently experiencing diarrhoea or develop diarrhoea while using **SEPENCIL**. This may be an indication of inflammation of the large intestine (colitis). Please consult your doctor immediately.

SEPENCIL is not recommended in children under the age of 3 months or children with kidney disorders.

Pregnancy and Breastfeeding:

DO NOT use **SEPENCIL** if you are pregnant, planning to become pregnant or breastfeeding.

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SEPENCIL is excreted into breast milk and may affect your baby. Please consult your doctor.

Driving and using machinery:

SEPENCIL may affect your ability to drive a car or operate machinery (See **POSSIBLE SIDE EFFECTS**). Do take care until you know how **SEPENCIL** affects you.

Using other medicines with SEPENCIL:

Always tell your healthcare professional if you are taking any other medicine. (This includes any complementary or traditional medicines).

SEPENCIL may interact with the following medicines:

- warfarin – it may cause your blood to thin further
- penicillins or cephalosporins – antibiotics which may cause **SEPENCIL** to be less effective
- probenecid – used to treat gout
- ganciclovir (antiviral medicine), valproic acid or sodium valproate (both used to treat mental disorders) – your risk of having seizures (fits) may be increased if you take any of these medicines with **SEPENCIL**

4. HOW TO RECEIVE SEPENCIL

Your doctor will decide on the correct dose to obtain the needed result and how long the treatment will be.

To clear up your infection completely, **SEPENCIL** will be administered for the full course of treatment, even if you feel better in a few days. Your doctor will let you know when treatment will be stopped.

You will not be expected to give yourself **SEPENCIL**. It will be given to you by a person who is qualified to do so. **SEPENCIL** is given as an injection into a vein (intravenous) and will be

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administered in hospital. Each vial is for single use only.

If you receive more SEPENCIL than you should

Since your healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If an SEPENCIL infusion was not given to you

Your doctor will make sure you receive **SEPENCIL** at the correct time. If you are concerned that you may have missed a dose, contact your doctor immediately.

5. POSSIBLE SIDE EFFECTS

SEPENCIL can have side effects.

Not all side effects reported for **SEPENCIL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor or healthcare professional immediately:

- swelling of hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SEPENCIL**. You may need urgent medical attention.

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

- serious diarrhoea (for longer than two weeks, bloody or watery diarrhoea, abdominal cramps and pain), sign of recurrent infection
- seizures (fits), brain disease, damage or malfunction possibly characterised by difficulty

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focussing, memory loss or trouble with problem solving skills

- very fast or hard heartbeat, skipping a heartbeat, blue or purplish skin colouration
- fast or deep breathing, shortness of breath
- liver disorders and/or failure possibly characterised by confusion, extreme irritability, altered consciousness, blood clotting defects and fluid build-up in arms, legs or abdomen
- painful red/purplish rash that spreads or blisters, detachment of the upper layer of skin from the lower layer of skin, peeling of the skin over large areas of the body
- worsening of a rare disease characterised by muscle weakness
- kidney disorders (you may pass less or more urine than is normal for you) These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- fungal infection
- blood disorders (may cause you to feel unwell)
- seeing things that aren't there, confusional state, sleepiness
- sudden muscle contractions, dizziness, headache, distorted sense of taste, tingling sensation (pins and needles)
- hearing loss, a feeling of spinning/swirling, noise or ringing in the ear
- blood clots in one or more of your veins, low blood pressure
- nausea, vomiting, diarrhoea, staining of teeth and/or tongue, abdominal pain, soreness of tongue, heart burn
- minor skin conditions like redness of skin, itchy skin, pale red bumps, rash
- chronic pain in more than one joint in the body, chest discomfort

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- reddish urine pain, inflammation and tenderness at the site of injection redness of skin, lack of energy, fever

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF SEPENCIL Sterile Powder

Store at or below 25 °C and protect from light.

Do not freeze. Keep vial in the outer carton until required for use.

Reconstituted Solution

Reconstituted solutions may be stored at 25 °C for 4 hours or 24 hours at 2 – 8 °C (in a refrigerator). Discard any unused solution.

SEPENCIL should not be mixed with or physically added to other antibiotics.

KEEP OUT OF SIGHT AND REACH OF CHILDREN