PATIENT INFORMATION LEAFLET

SEPENCIL RANGE

SCHEDULING STATUS:

S4

SEPENCIL 250 mg powder for solution for infusion

SEPENCIL 500 mg powder for solution for infusion

Imipenem / cilastatin

Sugar free

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, nurse or other healthcare provider.
- 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.

What is in this leaflet

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

1. What SEPENCIL is and what it 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 infections, bone and joint infections. It is also used preventatively prior to certain surgical procedures.

2. What you need to know before you are administered SEPENCIL

SEPENCIL should not be administered to you:

- if you are hypersensitive (allergic) to imipenem or cilastatin or any of the other ingredients of SEPENCIL (see section 6)
- if you are allergic to other antibiotics such as penicillins, cephalosporins, or carbapenems
- if you are pregnant, are planning to become pregnant, or are breastfeeding (see Pregnancy and breastfeeding)
- if you have meningitis.

Warnings and precautions

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

- if you are allergic to any medicines, including antibiotics (sudden life-threatening allergic reactions require immediate medical treatment)
- if you have meningitis (an alternate antibiotic should be used)
- if you have any central nervous system (CNS) disorder, such as seizures
- if you have kidney problems, including reduced kidney function
- if you have liver problems
- 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.

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 and adolescents

SEPENCIL is not recommended in children less than 3 months of age or in children with kidney problems.

Other medicines and SEPENCIL

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

SEPENCIL may interact with the following medicines:

- Warfarin (a medicine used as blood thinner), as it may cause your blood to thin further
- Penicillins or cephalosporins – antibiotics which may cause SEPENCIL to be less effective
- Probenecid (a medicine used to treat gout)
- Ganciclovir (a medicine used to treat some viral infections), valproic acid or sodium valproate (medicines used to treat mental disorders or epilepsy) – your risk of having seizures (fits) may be increased if you take any of these medicines with SEPENCIL.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Do not use SEPENCIL if you are pregnant. SEPENCIL is excreted into breast milk and may affect your baby. If you are breastfeeding, please consult your doctor before SEPENCIL is given to you.

Driving and using machines

SEPENCIL can cause dizziness, seizures, confusional states and hallucinations which may affect your ability to drive or operate machines (see Possible side effects). Do not drive or operate any tools or machines until you know how SEPENCIL affects you.

It is not always possible to predict to what extent SEPENCIL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SEPENCIL affects them.

SEPENCIL contains sodium

SEPENCIL 250 mg contains 18,8 mg sodium in each vial.

SPENCIL 500 mg contains 37,6 mg sodium in each vial.

Sodium is the main component of table salt. This is equivalent to 0,94 % and 1,88 %, respectively, of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive SEPENCIL

You will not be expected to give yourself SEPENCIL. It will be given to you by a person who is qualified to do so.

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.

SEPENCIL is given as an injection into a vein (intravenous) and will be administered in hospital.

Each vial is for single use only.

If you are administered more SEPENCIL than you should

Since a healthcare provider will administer SEPENCIL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use SEPENCIL

Since a healthcare professional will administer SEPENCIL, it is unlikely that the dose will be missed.

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.

If you stop using SEPENCIL

Your doctor will let you know when treatment will be stopped.

4. 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 healthcare provider for advice.

If any of the following happens, stop using SEPENCIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the 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 or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- serious diarrhoea (for longer than two weeks, bloody or watery diarrhoea, stomach cramps and pain), sign of repeated infection
- seizures (fits), brain disease, damage or malfunction possibly characterised by difficulty 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, yellowing of your skin or eyeballs, nausea, fever, stomach swelling (hepatitis)
- an allergic reaction called Kounis syndrome (you may experience symptoms such as chest discomfort, acute chest pain, faintness, headache, nausea and dyspnoea).
- 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
- severe skin rash with loss of skin and hair (exfoliative dermatitis)
- worsening of a rare disease characterised by muscle weakness
- kidney problems (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:

Frequent side effects:

- blood disorders (may cause you to feel unwell)
- blood clots in one or more of your veins
- nausea, vomiting, diarrhoea
- rash

Less frequent side effects:

- fungal infection
- blood disorders (low white blood cell count)
- seeing things that aren’t there, confusional state, sleepiness
- sudden muscle contractions, dizziness, headache, distorted sense of taste, tingling sensation (pins and needles)

- uncontrollable shaking of your hands, arms and other body parts (focal tremor)
- hearing loss, a feeling of spinning/swirling, noise or ringing in the ear
- low blood pressure
- throat pain
- staining of your teeth or tongue
- stomach pains, heartburn
- increase in saliva
- skin blisters in a clustered arrangement on the face and possibly perineum, that may spread to the limbs, trunk, hands, feet, and scalp (linear IgA bullous disease)
- minor skin conditions like redness of skin, itchy skin, pale red bumps, rash, changes in the texture of the skin
- more or less urine than what is normal for you
- chronic pain in more than one joint in the body, chest discomfort
- itchy vulva
- inflammation and tenderness at the site of injection, redness of skin
- lack of energy
- fever.

The following side effects have been reported but the frequency for them to occur is not known:

- nervousness or feeling uneasy
- uncontrolled movements of the face, arms or legs.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to

SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

By reporting side effects, you can help provide more information on the safety of SEPENCIL.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store SEPENCIL

Store all medicines out of reach of children.

Powder for solution for infusion:

- Store at or below 25 °C.
- Protect from light.
- Do not freeze.
- Keep the vial in the outer carton until required for use.
- Do not use after the expiry date stated on the label.

Reconstituted solution:

- Reconstituted solutions may be stored at 25 °C for 4 hours or 24 hours at 2 - 8 °C (in a refrigerator).
- Do not freeze the reconstituted solution.
- SEPENCIL should not be mixed with or physically added to other antibiotics.
- Discard any unused solution.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SEPENCIL contains:

The active substances are imipenem and cilastatin.

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

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

The other substance is sodium bicarbonate.

What SEPENCIL looks like and contents of the pack

Before reconstitution:

White to light yellow homogeneous powder free from extraneous particles.

After reconstitution:

Clear, colourless to pale yellow solution, free from particles.

SEPENCIL 250 mg: Clear, colourless, 20 ml glass vial (Type I) with a grey butyl rubber stopper and sealed with an aluminium seal and a red coloured flip-off top.

SEPENCIL 500 mg: Clear, colourless, 20 ml glass vial (Type I) with a grey butyl rubber stopper and sealed with an aluminium seal and a green coloured flip-off top.

Holder of Certificate of Registration

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SEPENCIL 250 mg: A44/20.1.1/0813*

SEPENCIL 500 mg: A44/20.1.1/0814

*Not marketed.