

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CILNEM™

500 mg/500 mg Powder for Solution for Infusion

Imipenem /Cilastatin

Sugar free

Read all of this leaflet carefully before you are given CILNEM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

What is in this leaflet

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

1. What CILNEM is and what it is used for

CILNEM is an antibiotic medicine of the carbapenem group of antibiotics. It kills a wide range of bacteria (germs) that cause infections in various parts of the body.

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

- Infection in the abdomen

- Infection affecting the lungs (pneumonia)
- Infections that you can catch during or after the delivery of your baby
- Septicaemia (bacterial infection of the blood)
- Genitourinary tract infections
- Bone and joint infections
- Skin and soft tissue infections
- Bacterial infection of the lining of the heart cavity and valves (endocarditis)
- Mixed infections
- Prevention of certain post-operative infections.

2. What you need to know before you use CILNEM

CILNEM should not be administered to you:

- if you are allergic (hypersensitive) to imipenem, cilastatin or any of the other ingredients of CILNEM (listed in section 6)
- if you are allergic (hypersensitive) to other antibiotics such as penicillins, cephalosporins, or carbapenems
- if you have meningitis (infection in the membranes that cover the brain and spinal cord)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or healthcare provider before CILNEM is given to you, if you have:

- allergies to any medicines including antibiotics (sudden life-threatening allergic reactions require immediate medical treatment)
- colitis (inflammation of the bowels) or any other gastrointestinal disease

- any central nervous system disorders such as localised tremors or epileptic seizures
- kidney or urinary problems, including reduced kidney function (CILNEM 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)
- 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 explain this to you.

Tell your doctor if you are taking medicines called valproic acid or divalproex sodium (see “Other medicines and CILNEM”).

Use in children

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

Other medicines and CILNEM

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

Tell your doctor if you are taking:

- ganciclovir, which is used to treat some viral infections
- valproic acid or divalproex sodium (used to treat epilepsy, bipolar disorder, migraine, or schizophrenia)
- blood thinners such as warfarin
- probenecid (a medicine used for gout).

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

Pregnancy, breastfeeding and fertility

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

CILNEM has not been studied in pregnant women. CILNEM should therefore not be used during pregnancy (see “CILNEM should not be administered to you”).

CILNEM may pass into breastmilk and it may affect the baby. It is important to tell your doctor if you are breastfeeding or if you intend to breastfeed your baby.

There is no information available on the effect of CILNEM on fertility.

Driving and using machines

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

CILNEM contains sodium

CILNEM contains 1,6 millimole (approximately 37,6 mg) sodium per 500 mg dose (one vial). Tell your doctor if you are on a controlled sodium diet.

3. HOW TO USE CILNEM

Do not share medicine prescribed for you with any other person.

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

Your doctor will decide how much CILNEM you need. This will depend upon your condition and the severity of your infection.

Adults and adolescents

The usual daily dose is 1 - 2 g administered in 3 - 4 divided doses.

If you have kidney problems or if you weigh less than 70 kg, your doctor may lower your dose.

Children

The usual dose for children and infants (3 months or older) is 15 mg/kg every 6 hours.

CILNEM is not recommended in children under 3 months of age and children with kidney problems.

Method of administration

CILNEM is given intravenously (into a vein) over 20 to 30 minutes for a dose of 500 mg or less, or 40 to 60 minutes for a dose of 500 mg or more. The rate of infusion may be slowed if you feel sick.

If you are given more CILNEM than you should

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

If you miss a dose of CILNEM

Since a healthcare provider will administer CILNEM, it is unlikely that a dose will be missed.

However, if you are concerned that you may have missed a dose, contact your doctor or another healthcare provider immediately.

4. Possible side effects

CILNEM can have side effects.

Not all side effects reported for CILNEM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CILNEM, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor, as CILNEM should be stopped 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)
- Yellowing of your skin or eyeballs, nausea, fever, stomach swelling (hepatitis, abnormal)
- Severe watery diarrhoea, fever, abdominal pain (pseudomembranous colitis) or bloody diarrhoea (haemorrhagic colitis).

These are all very serious side effects. If you have them, you may have had a serious reaction to CILNEM. You may need urgent medical attention or further hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Increase in some white blood cells (eosinophilia)
- Swelling and redness along a vein which is extremely tender when touched
- Nausea, vomiting, diarrhoea
- Abnormal liver function detected by blood tests
- Rash

Less frequent side effects:

- Fungal infection (candidiasis)
- Changes in the amounts of various types of blood cells
- 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)
- Psychic disturbances (such as mood swings and impaired judgment)
- Seeing, hearing or feeling something that is not there (hallucinations)
- Confusion
- Sleepiness
- Seizures
- Tremors and uncontrolled twitching of muscles
- Dizziness
- Disease of the brain, tingling sensation (pins and needles), localised tremor
- Worsening of a rare disease associated with muscle weakness (aggravation of myasthenia gravis)
- Headache
- Hearing loss, ringing in the ears (tinnitus)
- Sensation of spinning (vertigo)
- Irregular heartbeat, the heart beating forcefully or rapidly
- Low blood pressure
- Flushing
- Abnormally fast and superficial breathing, difficulty breathing, chest discomfort
- Staining of the teeth and/or tongue

- Red swollen tongue, overgrowth of the normal projections on the tongue giving it a hairy appearance, heartburn, sore tongue, increase in the production of saliva, disturbances in taste
- Abdominal pain, heartburn
- Inability of the liver to perform normal function
- Local skin redness
- Excessive sweating, skin texture changes
- Skin itchiness
- Hives
- Pain in several joints, pain in the upper spine
- Inability of the kidney to perform normal function, changes in the amount of urine, changes in urine colour
- Itching of the vulva in women
- Fever
- Local pain and formation of a firm lump at the injection site
- Weakness
- Abnormal kidney, liver and blood function detected by blood tests
- A positive Coombs test

Unknown frequency:

- Agitation
- Abnormal movements

If you notice any side effects not listed 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 SAHPRA website:

<https://www.sahpra.org.za/Publications/Index/8>.

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

5. How to store CILNEM

Store all medicines out of reach of children.

Store at or below 25 °C. Keep in carton to protect from light.

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 four hours.

Do not freeze the reconstituted solution.

Do not use after the expiry date stated on the label/carton. The expiry date refers to the last day of that month.

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 CILNEM contains

Each vial contains 500 mg imipenem (as imipenem monohydrate) and 500 mg cilastatin (as cilastatin sodium salt).

The other ingredient is sodium bicarbonate.

What CILNEM looks like and contents of the pack

CILNEM is a white to almost white or light yellow powder for solution for infusion, in a clear, colourless 20 ml glass vial with a bromobutyl stopper and an aluminium flip-off cap. The vials are packed in a carton containing 1 or 10 vials.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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