PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

IMIPENEM/CILASTATIN 250 mg/250 mg FRESENIUS

IMIPENEM/CILASTATIN 500 mg/500 mg FRESENIUS

Powder for Solution for Infusion

Imipenem /Cilastatin

Sugar free

- **Read all of this leaflet carefully before you are given IMIPENEM/ CILASTATIN FRESENIUS**.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or other healthcare provider.

What is in this leaflet

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

1. What IMIPENEM/CILASTATIN FRESENIUS is and what it is used for

IMIPENEM/CILASTATIN FRESENIUS is a carbapenem antibiotic medicine. It kills a wide range of bacteria (germs) that cause infections in various parts of the body.

IMIPENEM/CILASTATIN FRESENIUS may have been prescribed because you have one (or more) of the following types of complicated infections:

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

2. What you need to know before you use IMIPENEM/CILASTATIN FRESENIUS

IMIPENEM/CILASTATIN FRESENIUS should not be administered to you:

- if you are allergic (hypersensitive) to imipenem, cilastatin or any of the other ingredients of IMIPENEM/CILASTATIN FRESENIUS (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 being given the injection 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 (inflammation of the bowels) or any other gastrointestinal disease
- any central nervous system disorders such as localised tremors or epileptic seizures
- liver, kidney or urinary problems.

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.

Tell your doctor if you are taking medicines called valproic acid or divalproex sodium (see other medicines and IMIPENEM/CILASTATIN FRESENIUS).

Use in children

IMIPENEM/CILASTATIN FRESENIUS is not recommended in children less than 3 months of age or children with kidney problems.

Other medicines and IMIPENEM/CILASTATIN FRESENIUS

Always tell your healthcare provider 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.

Also, tell your doctor if you are taking valproic acid or divalproex sodium (used to treat epilepsy, bipolar disorder, migraine, or schizophrenia) or blood thinners such as warfarin, or probenecid (a medicine used for gout).

Your doctor will decide whether you should use IMIPENEM/CILASTATIN FRESENIUS 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 IMIPENEM/CILASTATIN FRESENIUS.

Imipenem/cilastatin has not been studied in pregnant women. IMIPENEM/CILASTATIN FRESENIUS should not be used during pregnancy (see “IMIPENEM/CILASTATIN FRESENIUS should not be administered to you”).

IMIPENEM/CILASTATIN FRESENIUS may pass into breastmilk and it may affect the baby. If you are breastfeeding or if you intend to breastfeed your baby, it is important to tell your doctor.

Driving and using machines

There are some side effects associated with this IMIPENEM/CILASTATIN FRESENIUS (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).

IMIPENEM/CILASTATIN FRESENIUS contains sodium

Imipenem/Cilastatin 250 mg/250 mg contains 0,8 mmol (18,8 mg) sodium per container and Imipenem/Cilastatin 500 mg/500 mg contains 1,6 mmol (37,5 mg) sodium per container. Tell your doctor if you are on a controlled sodium diet.

3. HOW TO USE IMIPENEM/CILASTATIN FRESENIUS

You will not be expected to give yourself IMIPENEM/CILASTATIN FRESENIUS.

IMIPENEM/CILASTATIN FRESENIUS will be prepared and given to you by a doctor or another healthcare provider. Your doctor will tell you how long your treatment with IMIPENEM/CILASTATIN FRESENIUS will last.

Adults and adolescents

Most infections respond to a daily dose of 1 000 – 2 000 mg administered in 3 - 4 divided doses. Your doctor will decide how much IMIPENEM/ CILASTATIN FRESENIUS you need. This will depend upon your condition and the severity of your infection.

If you have kidney problems or 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.

IMIPENEM/CILASTATIN FRESENIUS is not recommended in children under 3 months of age and children with kidney problems.

Method of administration

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

If you use more IMIPENEM/CILASTATIN FRESENIUS than you should

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

If you forget to use IMIPENEM/CILASTATIN FRESENIUS

Since a healthcare provider will administer IMIPENEM/CILASTATIN FRESENIUS, it is unlikely that the dose will be missed.

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

4. Possible side effects

IMIPENEM/CILASTATIN FRESENIUS can have side effects.

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

If any of the following happens, tell your doctor, as IMIPENEM/ CILASTATIN FRESENIUS 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. If these side effects occur while receiving or after receiving IMIPENEM/CILASTATIN FRESENIUS, the medicine must be stopped and your doctor contacted immediately.
- Skin peeling (toxic epidermal necrolysis)
- Severe skin reactions with blisters on the skin, mouth, nose, and eyes and sloughing (shedding) of skin (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)
- 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 IMIPENEM/CILASTATIN FRESENIUS. 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)

- Inflammation of the wall of a vein with associated thrombosis
- Nausea, vomiting, diarrhoea
- Abnormal liver function detected by blood tests
- Rash
- Swelling and redness along a vein which is extremely tender when touched

Less frequent side effects:

- Fungal infection (candidiasis)
- Changes in the amounts of various types of blood cells
- 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

- Flushing, bluish discoloration of the face and lips, skin texture changes, excessive sweating
- Low blood pressure
- Chest discomfort, difficulty breathing, abnormally fast and superficial breathing, pain in the upper spine
- 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, altered taste
- Disturbances in taste
- Inability of the liver to perform normal function
- Local skin redness
- Skin itchiness
- Hives
- Pain in several joints
- 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, redness, swelling and formation of a firm lump at the injection site
- Weakness
- 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)

- Abnormal kidney, liver and blood function detected by blood tests.

Not known 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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of IMIPENEM/CILASTATIN FRESENIUS.

5. How to store IMIPENEM/CILASTATIN FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C.

After reconstitution:

Diluted solutions should be used immediately.

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 IMIPENEM/CILASTATIN FRESENIUS contains

IMIPENEM/CILASTATIN 250 mg/250 mg FRESENIUS, powder for solution for infusion:

Each vial contains 250 mg imipenem (as 265 mg imipenem monohydrate) and 250 mg cilastatin (as 265 mg cilastatin sodium salt).

The other ingredient is sodium bicarbonate.

IMIPENEM/CILASTATIN 500 mg/500 mg FRESENIUS, powder for solution for infusion:

Each vial contains 500 mg imipenem (as 530 mg imipenem monohydrate) and 500 mg cilastatin (as 530 mg cilastatin sodium salt).

The other ingredient is sodium bicarbonate.

What IMIPENEM/CILASTATIN FRESENIUS looks like and contents of the pack

IMIPENEM/CILASTATIN FRESENIUS is a white to light (pale) yellow powder for solution for infusion in a glass vial. Pack sizes of 10 x 20 ml vials.

Holder of Certificate of Registration

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Imipenem/Cilastatin 250 mg/250 mg Fresenius – 47/20.1.1/1149

Imipenem/Cilastatin 500 mg/500 mg Fresenius – 47/20.1.1/1150

Access to the corresponding Professional Information

The professional information leaflet is included in the carton.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

IMIPENEM/CILASTATIN 250 mg/250 mg FRESENIUS

IMIPENEM/CILASTATIN 500 mg/500 mg FRESENIUS

Poeier vir oplossing vir infusie

Imipenem /Silastatien

Suiker-vry

Lees hierdie hele inligtingsblad aandagtig deur voordat IMIPENEM/ CILASTATIN FRESENIUS aan jou gegee word.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy enige verdere vrae het, vra jou dokter, apteker, of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad:

1. Wat is IMIPENEM/CILASTATIN FRESENIUS en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy IMIPENEM/ CILASTATIN FRESENIUS gebruik
3. Hoe om IMIPENEM/CILASTATIN FRESENIUS te gebruik
4. Moontlike newe-effekte
5. Hoe om IMIPENEM/ CILASTATIN FRESENIUS te bewaar
6. Inhoud van die pak en ander inligting

1. Wat is IMIPENEM/CILASTATIN FRESENIUS en waarvoor word dit gebruik

IMIPENEM/CILASTATIN FRESENIUS is ‘n karbapenem antibiotiese medisyne. Dit maak ‘n wye reeks bakterieë wat infeksies in verskeie dele van die liggaam veroorsaak, dood.

IMIPENEM/CILASTATIN FRESENIUS kan vir jou voorgeskryf word omdat jy een (of meer) van die volgende tipes gekompliseerde infeksies het:

- Infeksies van die buik (abdomen)
- Infeksies wat die longe beïnvloed (pneumonie)
- Ginekologiese infeksies wat jy kan opdoen tydens of na verlossing
- Septisemie (bakteriële bloedinfeksie)
- Genito-urinêre infeksies
- Been- en gewrigsinfeksies
- Vel- en sagteweefselinfeksies
- Endokarditis (bakteriële infeksies van die voering van die hartholte en -kleppe)
- Gemengde infeksies
- Voorkoming van sekere na-operatiewe infeksies.

2. Wat jy moet weet voordat jy IMIPENEM/CILASTATIN FRESENIUS gebruik

IMIPENEM/CILASTATIN FRESENIUS moet nie aan jou toegedien word nie:

- indien jy allergies (hipersensitief) is vir imipenem, silastatien of enige van die bestanddele van IMIPENEM/CILASTATIN FRESENIUS (gelys by afdeling 6).
- indien jy allergies (hipersensitief) vir ander antibiotika soos penisilliene, kefalosporiene of karbapeneme
- indien jy meningitis het (infeksie in die membrane wat die brein en rugmurg omhul)
- indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in oor enige mediese toestand wat jy het of gehad het voordat die inspuiting aan jou gegee word, insluitend:

- allergieë vir enige medisyne insluitend antibotika (skielike lewensbedreigende allergiese reaksies vereis onmiddellike mediese behandeling)

- kolitis (inflammasie van die derms) of enige ander gastroïntestinale siekte
- enige sentrale senuweestelselsteurings soos gelokaliseerde tremors of epileptiese aanvalle
- lewer-, nier- of urinêre probleme.

Jy kan ‘n positiewe toets (Coombs se toets) ontwikkel wat die teenwoordigheid van teenliggaampies wat die rooibloedselle kan vernietig, aandui. Jou dokter sal dit met jou bespreek.
Lig jou dokter in indien jy medisyne genaamd valproïensuur of natriumdivalproeks neem (sien Ander medisyne en IMIPENEM/CILASTATIN FRESENIUS).

Gebruik by kinders
IMIPENEM/CILASTATIN FRESENIUS word nie aanbeveel by kinders jonger as die ouderdom van 3 maande of kinders met nierprobleme nie.

Ander medisyne en IMIPENEM/CILASTATIN FRESENIUS
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Lig jou dokter in indien jy gansiklovir neem wat gebruik word om sekere virale infeksies te behandel.

Lig ook jou dokter in as jy valproïensuur of natriumdivalproeks neem (gebruik om epilepsie, bipolêre steuring, migraine, of skisofrenie te behandel) of bloedverdunners soos warfarien, of probenisied (‘n medisyne wat vir jig gebruik word).
Jou dokter sal besluit of jy IMIPENEM/CILASTATIN FRESENIUS in kombinasie met hierdie medisyne kan gebruik.

Swangerskap en borsvoeding en vrugbaarheid

Indien jy swanger is, of borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy IMIPENEM/CILASTATIN FRESENIUS ontvang.
Imipenem/silastatien is nie by swanger vroue bestudeer nie.
IMIPENEM/CILASTATIN FRESENIUS moet nie tydens swangerskap gebruik word nie (sien "IMIPENEM/CILASTATIN FRESENIUS moet nie aan jou toegedien word nie").
IMIPENEM/CILASTATIN FRESENIUS kan in borsmelk versprei en dit kan jou baba aantas. Indien jy borsvoed of daar aan dink om jou baba te borsvoed, is dit belangrik om jou dokter te vertel.

Bestuur en die gebruik van masjinerie

Daar is enkele newe-effekte wat met IMIPENEM/CILASTATIN FRESENIUS geassosieer word (soos iets sien, hoor of voel wat nie daar is nie, duiseligheid, slaperigheid en 'n sensasie van draaiing) wat jou vermoë om te bestuur of masjinerie te hanteer kan beïnvloed (sien afdeling 4).

IMIPENEM/CILASTATIN FRESENIUS bevat natrium

Imipenem/Cilastatin 250 mg/250 mg bevat 0,8 mmol (18,8 mg) natrium per houer en Imipenem/Cilastatin 500 mg/500 mg bevat 1,6 mmol (37,5 mg) natrium per houer. Lig jou dokter in indien jy op 'n gekontroleerde natriumdieet is.

3. Hoe om IMIPENEM/CILASTATIN FRESENIUS te neem

Daar sal nie van jou verwag word om IMIPENEM/CILASTATIN FRESENIUS aan jouself te gee nie.

IMIPENEM/CILASTATIN FRESENIUS sal voorberei en gegee word deur ‘n dokter of ander gesondheidsorgverskaffer. Jou dokter sal jou inlig hoe lank jou behandeling met IMIPENEM/CILASTATIN FRESENIUS sal duur.

Volwassenes en tieners

Meeste infeksies reageer op ‘n daaglikse dosis van 1 000 – 2 000 mg toegedien in 3 - 4 verdeelde dosisse. Jou dokter sal besluit hoeveel IMIPENEM/CILASTATIN FRESENIUS jy benodig. Dit sal afhang van jou toestand en die erns van jou infeksie.

Indien jy nierprobleme het of minder as 70 kg weeg kan jou dokter jou dosis verlaag.

Kinders

Die gebruiklike dosis vir kinders en babas (3 maande of ouer) is 15 mg/kg elke 6 uur. IMIPENEM/CILASTATIN FRESENIUS word nie aanbeveel by kinders jonger as die ouderdom van 3 maande en kinders met nierprobleme nie.

Toedieningsmetode

IMIPENEM/CILASTATIN FRESENIUS word intraveneus gegee (in ‘n aar) oor ‘n tydperk van 20 - 30 minute vir ‘n dosis van 500 mg/500 mg of minder, of 40 - 60 minute vir ‘n dosis van 500 mg/500 mg of meer. Die infusietempo kan stadiger gemaak word indien jy siek voel.

As jy meer IMIPENEM/CILASTATIN FRESENIUS gebruik het as wat jy moes

Aangesien jou gesondheidsorgverskaffer IMIPENEM/CILASTATIN FRESENIUS, sal toedien, sal hy/sy die dosis beheer**.** Nietemin, in geval van ‘n oordosering, sal jou dokter die oordosis behandel.

Indien jy vergeet het om IMIPENEM/CILASTATIN FRESENIUS te gebruik

Aangesien 'n gesondheidsorgverskaffer IMIPENEM/CILASTATIN FRESENIUS sal toedien is dit onwaarskynlik dat ‘n dosis oorgeslaan sal word. Indien jy egter bekommerd is dat ‘n dosis oorgeslaan is, kontak jou dokter of enige ander gesondheidsorgverskaffer onmiddellik.

4. Moontlike newe-effekte

IMIPENEM/CILASTATIN FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir IMIPENEM/CILASTATIN FRESENIUS aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy IMIPENEM/CILASTATIN FRESENIUS ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, lig jou dokter in aangesien IMIPENEM/CILASTATIN FRESENIUS onmiddellik gestaak moet word:

- Allergiese reaksies insluitend uitslag, swelling van die gesig, lippe, tong en/of keel (met moeilike asemhaling of sluk), en/of lae bloeddruk. Indien hierdie newe-effekte voorkom terwyl jy IMIPENEM/CILASTATIN FRESENIUS ontvang of daarna, moet die medisyne gestaak word en jou dokter onmiddellik gekontak word.
- Velafskilfering (toksiese epidermale nekrolise)
- Ernstige velreaksies met blase op die vel, mond, neus en oë en vervel (afskilfer) van vel (Stevens-Johnson se sindroom en erytherma multiforme)
- Ernstge veluitslag met verlies van vel en hare (eksfoliatiewe dermatitis)
- Vergeling van jou vel of oogballe, naarheid, koors, maagswelling (hepatitis)
- Ernstige waterige diarree, koors, buikpyn (pseudomembraneuse kolitis) of bloederige diarree (hemorragiese kolitis).

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik ’n ernstige allergiese reaksie op IMIPENEM/CILASTATIN FRESENIUS hê. Jy kan dringende mediese aandag of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- Toename in enkele witbloedselle (eosinofilie)
- Inflammasie van die wand van ‘n aar met geassosieerde trombose
- Naarheid, braking, diarree
- Abnormale lewerfunksie wat met bloedtoeste vasgestel word
- Uitslag
- Swelling en rooiheid langs ‘n aar wat uiters gevoelig is wanneer dit aangeraak word

Minder dikwelse newe-effekte:

- Fungusinfeksie (kandidiase)
- Veranderinge in die hoeveelhede van verskillende tipes bloedselle
- Psigiese veranderinge (soos gemoedsveranderinge en aangetaste oordeel)
- Iets sien, hoor en voel wat nie daar is nie (hallusinasies)
- Verwarring
- Slaperigheid
- Aanvalle
- Tremors en ongekontroleerde spiertrekkings
- Duiseligheid
- Siekte van die brein, tintelende sensasie (spelde en naalde), gelokaliseerde tremor
- Verergering van ‘n skaars siekte geassosieer met spierswakheid (verergering van myasthenia gravis)
- Hoofpyn

- Gehoorverlies, gesuis in die ore (tinnitus)
- Sensasie van draaiing (vertigo)
- Onreëlmatige hartklop, hart klop kragtig of vinnig
- Blosing, blouerige verkleuring van die gesig en lippe, veltekstuurveranderinge, oormatige sweet.
- Lae boeddruk
- Borsongemak, moeilike asemhaling, abnormale vinnige en oppervlakkige asemhaling, pyn in die boonste ruggraat
- Tande en/of die tong wat vlek
- Rooi, geswelde tong, oorgroeiing van die normale projeksies op die tong wat dit ‘n harige voorkoms gee, sooibrand, seer tong, verhoogde produksie van speeksel en veranderde smaak
- Steurnis in smaak
- Onvermoë van die lewer om normale funksie uit te voer
- Lokale rooiheid van die vel
- Gejeuk van die vel
- Jeukbulte
- Pyn in verskeie gewrigte
- Onvermoë van die nier om normale funksie uit te voer, verandering in die hoeveelheid urien, veranderinge in die urienkleur
- Gejeuk van die vulva by vrouens
- Koors
- Lokale pyn, rooiheid, swelling en vorming van ‘n stewige knop by die inspuitingplek
- Swakheid
- Bloedversteurings wat die selkomponente van die bloed beïnvloed en gewoonlik deur bloedtoetse vasgestel word (simptome kan moegheid, bleekheid van die vel, en verlengde kneusing na besering wees)

- Abnormale nier-, lewer- en bloedfunksie wat met bloedtoetse vasgestel word.

Newe-effekte wat met onbekende frekwensie voorkom:

- Agitasie
- Abnormale bewegings.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, raadpleeg jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van IMIPENEM/CILASTATIN FRESENIUS te verskaf.

5. Hoe om IMIPENEM/CILASTATIN FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 25 °C.

Na hersamestelling:

Verdunde oplossings moet dadelik gebruik word. Moenie gebruik na die vervaldatum wat op die karton of etiket gedruk is nie. Die vervaldatum verwys na die laaste dag van die maand.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat IMIPENEM/CILASTATIN FRESENIUS bevat

IMIPENEM/CILASTATIN 250 mg/250 mg FRESENIUS, poeier vir oplossing vir infusie:

Elke flessie bevat 250 mg imipenem (as 265 mg imipenemmonohidraat) en 250 mg silastatien (as 265 mg silastatiennatriumsout).

Die ander bestanddeel is natriumbikarbonaat.

IMIPENEM/CILASTATIN 500 mg/500 mg FRESENIUS, poeier vir oplossing vir infusie:

Elke flessie bevat 500 mg imipenem (as 530 mg imipenemmonohidraat) en 500 mg silastatien (as 530 mg silastiennatriumsout).

Die ander bestanddeel is natriumbikarbonaat.

Hoe IMIPENEM/CILASTATIN FRESENIUS lyk en inhoud van die verpakking

IMIPENEM/CILASTATIN FRESENIUS is ‘n wit tot lig (bleek)-geel poeier vir oplossing vir infusie in ‘n glasflessie. Verpakkingsgroottes van 10 x 20 mL flessies.

Houer van die Registrasiesertifikaat

Fresenius Kabi South Africa (Pty) Ltd

Erf 7 Growthpoint Business Park

Tonettistraat 162

Halfway House Extension 7

Midrand 1685

Gauteng

Suid-Afrika

Telefoonnommer: +27 (0)11 545 0000

Hierdie inligtingsblad is laas hersien in

Registrasie datum: 30 Maart 2021

Registrasienommers

Imipenem/Cilastatin 250 mg/250 mg Fresenius – 47/20.1.1/1149

Imipenem/Cilastatin 500 mg/500 mg Fresenius – 47/20.1.1/1150

Toegang tot die ooreenstemmende Professionele inligtingsblad

Die professionele inligting sal gedruk word en saam met die produk verpak word.