PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MEROPENEM 500 mg FRESENIUS

MEROPENEM 1 000 mg FRESENIUS

Sterile powder for solution for injection or infusion

Sugar free

Read all of this leaflet carefully before you are given MEROPENEM FRESENIUS

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

What is in this leaflet:

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

1. What MEROPENEM FRESENIUS is and what it is used for

Meropenem belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections in adults and children, which may occur in the lungs, bladder and kidney, abdomen, skin, brain, female reproductive organs.

MEROPENEM FRESENIUS may be used in the management of neutropenic patients (patients with low levels of white blood cells) with fever that is suspected to be due to a bacterial infection.

MEROPENEM FRESENIUS may be used to treat bacterial infection of the blood which might be associated with one of the infections mentioned above.

For certain infections your doctor may also prescribe an aminoglycoside type of antibiotic.

2. What you need to know before you use MEROPENEM FRESENIUS

Do not use MEROPENEM FRESENIUS:

- if you are allergic (hypersensitive) to meropenem or any of the other ingredients of MEROPENEM FRESENIUS (listed in section 6).
- if you are allergic (hypersensitive) to meropenem or any other carbapenem antibiotic, or any other type of beta-lactam antibiotic such as penicillin, or cephalosporin.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given the injection:

- if you have liver problems;
- if you have previously had severe diarrhoea after taking other antibiotics;
- if you have nervous system problems such as brain disorders or fits (seizures) (see "**Possible side effects**");
- if you have kidney problems or receive dialysis for kidney failure, as your doctor may want to adapt your dose;
- if you have a condition which requires you to monitor your sodium intake, please inform your doctor or nurse.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before MEROPENEM FRESENIUS is administered to you.

You may develop a positive blood test ("Coombs test") which indicates the presence of antibodies that may destroy red blood cells. Your doctor will discuss this with you.
You may develop signs and symptoms of severe skin reactions (see section 4). If this happens talk to your doctor or nurse immediately so that they can treat the symptoms.

Other medicines and MEROPENEM FRESENIUS

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

Tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- Probenecid (used to treat gout).
- Valproic acid/sodium valproate (used to treat epilepsy). MEROPENEM FRESENIUS should not be used because it may decrease the effect of sodium valproate.
- Anti-coagulants (used to treat or prevent blood clots) taken by mouth.

Pregnancy and breastfeeding

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 receiving MEROPENEM FRESENIUS.

The safety of MEROPENEM FRESENIUS during pregnancy has not been established.

It is important that you tell your doctor if you are breastfeeding or if you intend to breastfeed before receiving MEROPENEM FRESENIUS. Small amounts of meropenem may pass into the breast milk and it may affect the baby. You should therefore not breastfeed your baby if you have to be treated with MEROPENEM FRESENIUS, or your doctor may decide on another treatment if you continue breastfeeding.

Driving and using machines

MEROPENEM FRESENIUS has been associated with headache and tingling or pricking skin (paraesthesia). Any of these side effects could affect your ability to drive or operate machines.

MEROPENEM FRESENIUS may cause involuntary muscle movements which may cause the person's body to shake rapidly and uncontrollably (convulsions). This is usually accompanied with a loss of consciousness.

Do not drive or use machines if you experience these side effects.

MEROPENEM FRESENIUS contains sodium

MEROPENEM 500 mg FRESENIUS contains approximately 45,13 mg sodium (main component of cooking/table salt) in each vial/bottle. This is equivalent to 2,3 % of the recommended maximum daily dietary intake of sodium for an adult.

MEROPENEM 1 000 mg FRESENIUS contains approximately 90,25 mg sodium (main component of cooking/table salt) in each vial/bottle. This is equivalent to 4,5 % of the recommended maximum daily dietary intake of sodium for an adult.

If you have a condition which requires you to monitor your sodium intake, such as hypertension, please inform your doctor or nurse.

3. How to use MEROPENEM FRESENIUS

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

Your doctor will tell you how long your treatment with MEROPENEM FRESENIUS will last.

Use in adults

The dose depends on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will decide on the dose that you need. The usual dose for adults is between 500 mg (milligrams) and 1 000 mg (milligrams). You will usually receive a dose every 8 hours. However, you may receive a dose less often if your kidneys do not work very well.

Use in children and adolescents

The dose for children over 3 months old and up to 12 years of age is based on the age and weight of the child. The usual dose is between 10 mg and 40 mg of MEROPENEM FRESENIUS for each kilogram (kg) that the child weighs. A dose is usually given every 8 hours. Children who weigh over 50 kg will be given an adult dose.

There is no experience in children with renal problems.

Safety and efficacy in babies under 3 months have not been established and MEROPENEM FRESENIUS is therefore not recommended in this age group.

How MEROPENEM FRESENIUS will be given

MEROPENEM FRESENIUS will be given to you as an injection or infusion into a large vein.

You will not be expected to give yourself MEROPENEM FRESENIUS. It will be given to you by a healthcare provider who is qualified to do so.

Your doctor or nurse will normally give MEROPENEM FRESENIUS to you.

Your injection should not be mixed with or added to solutions that contain other medicines.

The injection may take about 5 minutes or between 15 and 30 minutes.

You should normally have your injections at the same times each day.

If you use more MEROPENEM FRESENIUS than you should

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

If you forget to use MEROPENEM FRESENIUS

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

Do not receive a double dose (two injections at the same time) to make up for a forgotten dose.

If you stop using MEROPENEM FRESENIUS

Do not stop having MEROPENEM FRESENIUS until your doctor tells you to, because resistant germs will stay behind if you do not complete a course of treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

MEROPENEM FRESENIUS can have side effects.

Not all side effects reported for MEROPENEM FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using MEROPENEM FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, tell your doctor or nurse immediately, as he/she may decide to stop administering MEROPENEM FRESENIUS:

Severe allergic reactions:

The signs may include a sudden onset of:

- Severe rash, itching or hives on the skin.
- Swelling of the face, lips, tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.
- Serious skin reactions which include:
    - Serious hypersensitivity reactions involving fever, skin rash, and changes in the blood tests that check how the liver is working (increased levels of liver enzymes) and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs of a multi-organ sensitivity disorder known as DRESS syndrome.
    - Severe red scaly rash, itching, skin bumps that contain pus, blisters or peeling of the skin. This may be associated with a high fever and joint pains.
    - Serious severe skin rashes that can appear as reddish circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome) or a more severe form (toxic epidermal necrolysis).

Damage to red blood cells:

The signs include:

- being breathless when you do not expect it
- red or brown urine (haemolytic anaemia).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Abdominal (stomach) pain.
- Diarrhoea.
- Being sick (vomiting).
- Feeling sick (nausea).
- Headache.
- Skin rash, itchy skin.
- Pain and inflammation.
- Increased numbers of platelets in your blood (shown in a blood test).
- Changes in blood tests, including tests that show how well your liver is working.

Less frequent side effects

- Changes in your blood. These include reduced numbers of platelets (which may make you bruise more easily), increased numbers of some white blood cells, decreased numbers of other white cells and increased amounts of a substance called ‘bilirubin’. Your doctor may do blood tests from time to time.
- Changes in blood tests, including tests that show how well your kidneys are working.
- A tingling feeling (pins and needles).
- Infections of the mouth or the vagina that are caused by a fungus (thrush).
- Delirium (an abrupt change in the brain that causes mental confusion).
- Inflammation of the bowel with diarrhoea.

- Pinpoint, round, red, brown or purple spots that appear on the skin as a result of bleeding.
- Purple spots (blood spots, which occur when small blood vessels burst, causing blood to pool under the skin).
- Sweating.
- Flushing.
- Inflammation of a vein that occurs when a blood clot forms.
- Sore veins where MEROPENEM FRESENIUS is injected.
- Other changes in your blood. The symptoms include frequent infections, high temperature and sore throat (agranulocytosis). Your doctor may do blood tests from time to time.
- Fits (convulsions).

Frequency not known (cannot be estimated from available data)

Increased liver enzymes and a type of white blood cell (eosinophilia), with enlarged lymph nodes. These may be signs of a multi-organ sensitivity disorder known as “DRESS”-syndrome.

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 SAHPRA website. By reporting side effects, you can help provide more information on the safety of MEROPENEM FRESENIUS.

You may report any suspected adverse drug reactions to your healthcare provider or the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the MEROPENEM FRESENIUS is marketed.

5. How to store MEROPENEM FRESENIUS

Store all medicines out of reach of children.

Dry powder

Store the dry powder at or below 25 °C and protect from light. Keep the vial/bottle in the outer container until required for use.

Reconstituted Solution

The product must be used immediately after first opening.

Do not freeze the reconstituted solution.

Injection

After reconstitution: The reconstituted solutions for intravenous injection should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous injection should not exceed:

- 3 hours when stored at room temperature up to 25 °C;
- 12 hours when stored under refrigerated conditions (2 – 8 °C).

Infusion

After reconstitution: The reconstituted solutions for intravenous infusion should be used immediately. The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed:

- 3 hours when stored at room temperature up to 25 °C when MEROPENEM FRESENIUS is dissolved in sodium chloride;
- 24 hours when stored under refrigerated conditions (2 - 8 °C) when MEROPENEM FRESENIUS is dissolved in sodium chloride;
- 1 hour when stored at room temperature up to 25 °C when MEROPENEM FRESENIUS is dissolved in dextrose solution;
- 8 hours when stored under refrigerated conditions (2 – 8 °C) when MEROPENEM FRESENIUS is dissolved in dextrose solution.

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbiological contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use MEROPENEM FRESENIUS after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What MEROPENEM FRESENIUS contains

The active substance is meropenem.

MEROPENEM 500 mg FRESENIUS:

Each 20 mL vial or 100 mL bottle contains 500 mg anhydrous meropenem as meropenem trihydrate.

MEROPENEM 1 000 mg FRESENIUS:

Each 20 mL vial or 100 mL bottle contains 1 000 mg anhydrous meropenem as meropenem trihydrate.

The other ingredient is anhydrous sodium carbonate.

What MEROPENEM FRESENIUS looks like and contents of the pack

MEROPENEM FRESENIUS is a white to light yellow powder.

MEROPENEM 500 mg FRESENIUS:

20 mL Type III colourless glass vials or 100 mL Type II colourless glass bottles, closed with bromobutyl rubber stoppers and sealed with 20 mm or 32 mm flip-off plastic-aluminium caps.

MEROPENEM 1 000 mg FRESENIUS:

20 mL Type III colourless glass vials or 100 mL Type II colourless glass bottles, closed with bromobutyl rubber stoppers and sealed with 20 mm or 32 mm flip-off plastic-aluminium caps.

Pack sizes of 1 or 10 vials/bottles.

Not all pack sizes may be marketed.

Holder of the Certificates of Registration

Fresenius Kabi SA (Pty) Ltd

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28 November 2023

Registration numbers

MEROPENEM 500 mg FRESENIUS: 48/20.1.1/0293

MEROPENEM 1 000 mg FRESENIUS: 48/20.1.1/0294

Access to the corresponding Professional Information

The professional information will be printed and supplied with the vial/bottle.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

MEROPENEM 500 mg FRESENIUS

MEROPENEM 1 000 mg FRESENIUS

Poeier vir oplossing vir inspuiting of infusie

Suikervry

Lees die hele inligtingsblad aandagtig deur voordat MEROPENEM FRESENIUS aan jou gegee word

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

Wat is in hierdie inligtingsblad:

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

1. Wat is MEROPENEM FRESENIUS en waarvoor word dit gebruik

Meropenem behoort tot 'n groep medisyne genaamd karbapenem-antibiotika. Dit werk deur bakterieë te dood wat ernstige infeksies in die longe, blaas en niere, buik, vel, brein en vroulike geslagsorgane by volwassenes en kinders kan veroorsaak.

MEROPENEM FRESENIUS kan gebruik word om pasiënte met neutropenie (pasiënte met lae witbloedseltellings) en koors, vermoedelik te wyte aan 'n bakteriële infeksie, te behandel.

MEROPENEM FRESENIUS kan gebruik word om 'n bakteriële bloedinfeksie te behandel wat verband kan hou met enige van die infeksies hierbo genoem.

Vir sekere infeksies kan jou dokter ook 'n aminoglikosied tipe antibiotikum voorskryf.

2. Wat jy moet weet voordat jy MEROPENEM FRESENIUS ontvang

Moet nie MEROPENEM FRESENIUS ontvang nie:

- indien jy allergies (hipersensitief) is vir meropenem of enige van die ander bestanddele van MEROPENEM FRESENIUS (gelys in afdeling 6).
- indien jy allergies (hipersensitief) is vir meropenem of ander karbapenem-antibiotika of ander tipes beta-laktaamantibiotika soos penisillien of kefalosporien.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter, apteker of verpleegster in voordat jy die inspuiting ontvang:

- indien jy lewerprobleme het;
- indien jy voorheen erge diarree gehad het nadat jy ander antibiotika geneem het;
- indien jy senuweestelselprobleme soos breinsiektes of stuipe (aanvalle) het (sien "**Moontlike newe-effekte**");
- indien jy nierprobleme het of dialise ontvang vir nierversaking, aangesien jou dokter dalk jou dosis wil aanpas;
- indien jy 'n mediese toestand het wat vereis dat jy jou natrium-inname moet monitor, lig asseblief jou dokter of verpleegster in.

Indien jy twyfel of enige van die bogenoemde op jou van toepassing is, raadpleeg jou dokter of verpleegster voordat MEROPENEM FRESENIUS aan jou toegedien word.

Jy kan 'n positiewe bloedtoets (Coombs-toets) ontwikkel, wat dui op die aanwesigheid van antiliggame wat rooibloedselle kan vernietig. Jou dokter sal dit met jou bespreek.
Jy kan tekens en simptome van ernstige velreaksies ontwikkel (sien afdeling 4). Indien dit gebeur, praat dadelik met jou dokter of verpleegster sodat hulle die simptome kan behandel.

Ander medisyne en MEROPENEM FRESENIUS

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Lig jou dokter, verpleegster of apteker in as jy enige van die volgende medisyne neem:

- Probenesied (gebruik vir die behandeling van jig).
- Valproïensuur/natriumvalproaat (gebruik vir die behandeling van epilepsie) MEROPENEM FRESENIUS moet nie gebruik word nie omdat dit die effek van natriumvalproaat kan verminder.
- Antistolmiddels (gebruik vir die behandeling of voorkoming van bloedklonte) geneem per mond.

Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy MEROPENEM FRESENIUS ontvang.

Die veiligheid van MEROPENEM FRESENIUS tydens swangerskap is nie bepaal nie.

Dit is belangrik dat jy voordat jy MEROPENEM FRESENIUS ontvang jou dokter inlig as jy borsvoeding gee of van plan is om jou baba te borsvoed. Klein hoeveelhede meropenem kan in die borsmelk voorkom en die baba beïnvloed. Jy moet dus nie jou baba borsvoed

as jy met MEROPENEM FRESENIUS behandel moet word nie, of jou dokter kan op 'n ander behandeling besluit as jy aanhou borsvoed.

Bestuur en die gebruik van masjinerie

MEROPENEM FRESENIUS is geassosieer met hoofpyn en tinteling of prikkelgevoel van die vel (parestesie). Enige van hierdie newe-effekte kan jou vermoë om te bestuur of masjiene te gebruik, beïnvloed.

MEROPENEM FRESENIUS kan onwillekeurige spierbewegings veroorsaak, waardeur die liggaam van die persoon vinnig en onbeheerbaar kan ruk (konvulsies). Dit gaan gewoonlik gepaard met 'n verlies van bewussyn.

Moenie bestuur of masjinerie gebruik as jy hierdie newe-effekte ervaar nie.

MEROPENEM FRESENIUS bevat natrium

MEROPENEM 500 mg FRESENIUS bevat ongeveer 45,13 mg natrium (hoofkomponent van kook/tafelsout) in elke flessie/bottel. Dit is gelykstaande aan 2,3 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

MEROPENEM 1 000 mg FRESENIUS bevat ongeveer 90,25 natrium (hoofkomponent van kook/tafelsout) in elke flessie/bottel. Dit is gelykstaande aan 4,5 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

Indien jy 'n mediese toestand het soos hipertensie, wat vereis dat jy jou natrium-inname moet monitor, lig asseblief jou dokter of verpleegster in.

3. Hoe om MEROPENEM FRESENIUS te gebruik

Daar sal nie van jou verwag word om MEROPENEM FRESENIUS aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.

Jou dokter sal jou inlig hoe lank jou behandeling met MEROPENEM FRESENIUS sal duur.

Gebruik by volwassenes

Die dosis hang af van die tipe infeksie wat jy het, waar die infeksie in die liggaam is en hoe ernstig die infeksie is. Jou dokter sal besluit oor die dosis wat jy benodig.
Die gewone dosis vir volwassenes is tussen 500 mg (milligram) en 1 000 mg (milligram). Jy sal gewoonlik elke 8 uur 'n dosis ontvang. Indien jou niere egter nie behoorlik werk nie, kan jy die dosis minder gereeld ontvang.

Gebruik by kinders en adolessente

Die dosis vir kinders ouer as 3 maande en tot 12 jaar hang af van die kind se ouderdom en gewig. Die gewone dosis is tussen 10 mg en 40 mg MEROPENEM FRESENIUS vir elke kilogram (kg) wat die kind weeg. 'n Dosis word gewoonlik elke 8 uur gegee. Kinders wat meer as 50 kg weeg, sal 'n volwasse dosis ontvang.
Daar is geen ondervinding by kinders met nierprobleme nie.
Veiligheid en doeltreffendheid by babas jonger as 3 maande is nie vasgestel nie en MEROPENEM FRESENIUS word dus nie vir hierdie ouderdomsgroep aanbeveel nie.

Hoe MEROPENEM FRESENIUS toegedien sal word

MEROPENEM FRESENIUS sal aan jou gegee word as 'n inspuiting of infusie in 'n groot aar.
Daar sal nie van jou verwag word om MEROPENEM FRESENIUS aan jouself toe te dien nie. Dit sal deur 'n gekwalifiseerde gesondheidswerker aan jou toegedien word.
Jou dokter of verpleegster sal normaalweg MEROPENEM FRESENIUS aan jou toedien.
Jou inspuiting moet nie gemeng of bygevoeg word by oplossings wat ander medisyne bevat nie.
Die inspuiting kan ongeveer 5 minute of tussen 15 en 30 minute duur.
Normaalweg moet jy jou inspuitings elke dag op dieselfde tyd kry.

Indien jy meer MEROPENEM FRESENIUS gebruik het as wat jy moes

Aangesien 'n gesondheidsorgverskaffer MEROPENEM FRESENIUS sal toedien, sal hy/sy die dosis beheer. In geval van 'n oordosering sal jou dokter egter die oordosering behandel.

Indien jy vergeet om MEROPENEM FRESENIUS te gebruik

Aangesien 'n gesondheidsorgverskaffer MEROPENEM FRESENIUS sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

Moenie 'n dubbele dosis (twee dosisse gelyktydig) ontvang om vergete individuele dosisse in te haal nie.

Indien jy ophou om MEROPENEM FRESENIUS te gebruik

Moenie behandeling met MEROPENEM FRESENIUS staak voordat jou dokter so sê nie, want as jy nie die behandelingskursus voltooi nie, sal weerstandbiedende kieme in die liggaam agterbly.

Indien jy enige verder vrae het oor die gebruik van hierdie medisyne, vra jou dokter, apteker of verpleegster.

4. Moontlike newe-effekte

MEROPENEM FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir MEROPENEM FRESENIUS aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy MEROPENEM FRESENIUS ontvang, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, lig jou dokter of verpleegster dadelik in, want hy/sy kan dan besluit om toediening van MEROPENEM FRESENIUS te staak:

Erge allergiese reaksies:

Die tekens kan 'n skielike aanvang wees van:

- Erge uitslag, jeuk of netelroos op die vel.
- Opgeswelde gesig, lippe, tong of ander dele van die liggaam.
- Kortasemigheid, hyging of moeilike asemhaling.
- Ernstige velreaksies wat insluit:
    - Ernstige hipersensitiwiteitsreaksies met koors, uitslag en veranderinge in bloedtoetse om lewerfunksie te kontroleer (verhoogde lewerensieme), 'n toename in 'n sekere tipe witbloedsel (eosinofilie) en vergrote limfknope. Dit kan tekens wees van 'n multi-orgaan sensoriese versteuring bekend as DRESS-sindroom.
    - Erge rooi, skubberige uitslag, jeuk, etterige velknoppies, blase of afskilferende vel. Dit kan geassosieer word met 'n hoë koors en gewrigspyn.
    - Ernstige veluitslag, wat kan voorkom as rooierige, sirkelvormige kolle (dikwels met blase in die middel) op die romp, afskilferende vel, sere in die mond, keel, neus, geslagsdele en oë; hierdie uitslag kan voorafgegaan word deur koors en griepagtige simptome (Stevens-Johnson-sindroom) of 'n ernstiger vorm (toksiese epidermale nekrolise).

Skade aan rooibloedselle:

Die tekens behels:

- asemloos wees wanneer jy dit nie verwag nie
- rooi of bruin urien (hemolitiese anemie).

Hierdie is almal baie ernstige newe-effekte. Indien jy dit ervaar, kan jy moontlik 'n ernstige reaksie op MEROPENEM FRESENIUS hê. Jy kan dringende mediese aandag of verdere hospitalisasie benodig.

Lig jou dokter in as jy enige van die volgende waarneem:

Gereelde newe-effekte

- Abdominale (maag) pyn.
- Diarree.
- Opbring (braking).
- Mislike gevoel (naarheid).
- Hoofpyn.
- Veluitslag, jeukende vel.
- Pyn en inflammasie.
- Verhoogde aantal plaatjies in jou bloed (aangetoon met 'n bloedtoets).
- Veranderinge in bloedtoetse, insluitend toetse wat aantoon hoe goed jou lewer werk.

Minder gereelde newe-effekte

- Veranderinge in jou bloed. Dit sluit in 'n verminderde aantal bloedplaatjies in die bloed (wat jou dan makliker laat kneus), 'n verhoogde aantal sekere witbloedselle, 'n verminderde aantal ander witbloedselle en verhoogde hoeveelhede van 'n stof genaamd "bilirubien". Jou dokter kan van tyd tot tyd bloedtoetse doen.
- Veranderinge in bloedtoetse, insluitend toetse wat aantoon hoe goed jou niere werk.
- Prikkelrige gevoel (speld-en-naaldprikkels).
- Infeksies van die mond of die vagina wat deur 'n swam (sproei) veroorsaak word.
- Delirium ('n skielike verandering in die brein wat geestelike verwarring veroorsaak).
- Inflammasie van die dikderm met diarree.
- Puntvormige, ronde, rooi, bruin of pers kolle wat as gevolg van bloeding op die vel verskyn.
- Pers kolle (bloedkolle, wat voorkom wanneer klein bloedvate bars, wat veroorsaak dat bloed onder die vel opdam).
- Sweet.
- Gloede.
- Ontsteking van 'n aar wat voorkom wanneer 'n bloedklont vorm.

- Seer are waar MEROPENEM FRESENIUS ingespuit word.
- Ander veranderinge in jou bloed. Die simptome sluit in gereelde infeksies, hoë temperatuur en seer keel (agranulositose). Jou dokter kan van tyd tot tyd bloedtoetse doen.
- Stuipe (konvulsies).

Frekwensie onbekend (kan nie uit die beskikbare gegewens beraam word nie)

Verhoogde lewerensieme en 'n tipe witbloedsel (eosinofilie) met vergrote limfknope. Dit kan tekens wees van 'n multi-orgaan gevoeligheidsversteuring bekend as "DRESS"-sindroom.

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 ondervind, bespreek dit met jou dokter, apteker of verpleegster. 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 oor die veiligheid van MEROPENEM FRESENIUS te verskaf.

Pasiënte word gevra om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om MEROPENEM FRESENIUS te bewaar

Berg alle medisyne buite bereik van kinders.

Droë poeier

Bewaar die droë poeier by of benede 25 °C en beskerm teen lig. Bewaar flessie/bottel in die buitehouer totdat dit benodig word vir gebruik.

Aangemaakte oplossing:

Die produk moet dadelik nadat dit oopgemaak is gebruik word.

Moenie die aangemaakte oplossing vries nie.

Inspuiting

Na hersamestelling: Die aangemaakte oplossings vir binneaarse inspuiting moet onmiddellik gebruik word. Die tydsinterval tussen die begin van die hersamestelling en die einde van die binneaarse inspuiting moet nie langer wees as:

- 3 ure indien bewaar by kamertemperatuur tot en met 25 °C;
- 12 ure indien in die yskas bewaar (2 - 8 °C).

Infusie

Na hersamestelling: Die aangemaakte oplossings vir binneaarse infusie moet onmiddellik gebruik word. Die tydsinterval tussen die begin van die hersamestelling en die einde van die binneaarse infusie moet nie langer wees as:

- 3 ure indien bewaar by kamertemperatuur tot en met 25 °C wanneer MEROPENEM FRESENIUS in natriumchloried-oplossing opgelos is nie;
- 24 uur wanneer dit in 'n yskas (2 - 8 °C) bewaar word wanneer MEROPENEM FRESENIUS in natriumchloried-oplossing opgelos is;
- 1 uur indien bewaar by kamertemperatuur tot en met 25 °C wanneer MEROPENEM FRESENIUS in dekstrose-oplossing opgelos is;
- 8 uur wanneer dit in 'n yskas (2 - 8 °C) bewaar word wanneer MEROPENEM FRESENIUS in dekstrose-oplossing opgelos is.

Vanuit 'n mikrobiologiese oogpunt moet die produk onmiddellik gebruik word, tensy die metode van oopmaak/hersamestelling/verdunning nie die risiko van mikrobiologiese kontaminasie uitskakel nie.
Indien dit nie onmiddellik gebruik word nie, is bewaartye en bergingstoestande tydens gebruik die verantwoordelikheid van die gebruiker.
Moenie MEROPENEM FRESENIUS na die vervaldatum wat op die houer verskyn gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

6. Inhoud van die pakkie en ander inligting

Wat MEROPENEM FRESENIUS bevat

Die aktiewe bestanddeel is meropenem.
MEROPENEM 500 mg FRESENIUS:
Elke 20 mL flessie of 100 mL bottel bevat 500 mg watervrye meropenem as meropenemtrihidraat.
MEROPENEM 1 000 mg FRESENIUS:
Elke 20 mL flessie of 100 mL bottel bevat 1 000 mg watervrye meropenem as meropenemtrihidraat.

Die ander bestanddeel is anhidriese natriumkarbonaat.

Hoe MEROPENEM FRESENIUS lyk en inhoud van die pakkie

MEROPENEM FRESENIUS is 'n wit tot liggeel poeier.

MEROPENEM 500 mg FRESENIUS:
20 mL Tipe III kleurlose glasbottels of 100 mL Tipe II kleurlose glasbottels, toegemaak met broombutielrubberproppe en verseël met 20 mm of 32 mm afdraaibare plastiek-aluminium-doppies.
MEROPENEM 1 000 mg FRESENIUS:

20 mL Tipe III kleurlose glasbottels of 100 mL Tipe II kleurlose glasbottels, toegemaak met broombutielrubberproppe en verseël met 20 mm of 32 mm afdraaibare plastiek-aluminium-doppies.

Verpakkingsgroottes 1 of 10 flessies/bottels.

Nie alle verpakkingsgroottes word bemark nie.

Houer van die Registrasiesertifikate

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Hierdie inligtingsblad was voorheen hersien op

28 November 2023

Registrasienommers

MEROPENEM 500 mg FRESENIUS: 48/20.1.1/0293

MEROPENEM 1 000 mg FRESENIUS: 48/20.1.1/0294

Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die flessie/bottel verskaf word.