Patient Information Leaflet

SCHEDULING STATUS: S4

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS

Powder for solution for infusion

Piperacillin

Tazobactam

Sugar free

Read all of this leaflet carefully before you are given PIPERACILLIN/TAZOBACTAM FRESENIUS

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

What is in this leaflet

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

1. What PIPERACILLIN/TAZOBACTAM FRESENIUS is and what it is used for

PIPERACILLIN/TAZOBACTAM FRESENIUS is used to treat moderate to severe infections caused by certain bacteria.

PIPERACILLIN/TAZOBACTAM FRESENIUS is an antibacterial medicine. It works by blocking the bacteria's cell wall growth, which kills the bacteria.

2. What you need to know before you are given PIPERACILLIN/TAZOBACTAM FRESENIUS

PIPERACILLIN/TAZOBACTAM FRESENIUS should not be given to you:

- if you are allergic (hypersensitive) to piperacillin or tazobactam or any of the ingredients of PIPERACILLIN/TAZOBACTAM FRESENIUS (listed in section 6)
- if you are allergic to penicillin or cephalosporin antibiotics, or to medicines called beta-lactamase inhibitors
- PIPERACILLIN/TAZOBACTAM FRESENIUS is not indicated for children below the age of 2 years.

Warnings and precautions

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

Special care should be taken with PIPERACILLIN/TAZOBACTAM FRESENIUS:

- if you are generally allergic to some medicines and/or foods, as serious or even fatal allergic reactions have occurred with PIPERACILLIN/TAZOBACTAM FRESENIUS
- if you experience diarrhoea after starting treatment with PIPERACILLIN/TAZOBACTAM FRESENIUS. Contact your doctor immediately as you may need to stop your treatment
- if you know that you have certain blood disorders, such as prolonged clotting time and low white blood cell count. Prolonged therapy with PIPERACILLIN/TAZOBACTAM FRESENIUS may cause decrease in white blood cells and increase your chance to get an infection

- if you know that you have low potassium levels in your blood. Your doctor may want to first check your kidneys and perform regular blood tests during treatment
- if you are receiving cancer treatment
- if you are taking diuretics (water tablets for heart problems or high blood pressure)
- if you are taking or using medicines such as heparin or warfarin to prevent blood clots (see "**Other medicines and PIPERACILLIN/TAZOBACTAM FRESENIUS**")
- if you are taking another antibiotic called vancomycin at the same time as PIPERACILLIN/TAZOBACTAM FRESENIUS, this may increase the risk of kidney injury (see also "**Other medicines and PIPERACILLIN/TAZOBACTAM FRESENIUS**")
- if you have a history of convulsions or fits as it may trigger an episode
- if you have a kidney disorder or if you are receiving haemodialysis. Your doctor may want to first check your kidneys and may perform regular blood tests during treatment
- if you have liver problems.

You should also know that:

PIPERACILLIN/TAZOBACTAM FRESENIUS may cause serious skin reactions such as red skin with blistering, peeling or loosening of the top layer, which may be life-threatening. (See section 4).

With high doses of PIPERACILLIN/TAZOBACTAM FRESENIUS you may get nervous system complications such as convulsions, especially if your kidneys do not work well. (See section 4).

There have been reports about a disease in which the immune system makes too many of otherwise normal white blood cells called histiocytes and lymphocytes, resulting in inflammation (haemophagocytic lymphohistiocytosis). This condition may be life-threatening if not diagnosed and treated early. If you experience multiple symptoms such as fever,

swollen glands, feeling weak, feeling lightheaded, shortness of breath, bruising, or skin rash, contact your doctor immediately.

Other medicines and PIPERACILLIN/TAZOBACTAM FRESENIUS

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking:

- Other antibiotics such as tetracycline, chloramphenicol, vancomycin, tobramycin.
  Tell your doctor if you have kidney problems. Taking PIPERACILLIN/TAZOBACTAM FRESENIUS and vancomycin at the same time may increase the risk of kidney injury even if you have no kidney problems.
- Probenecid (used for gout).
- Warfarin or other medicines to thin your blood.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.
- Vecuronium (muscle relaxant used in operations).
- Methotrexate (may be used in cancer treatment).
- Oral contraceptives, as efficacy of the oral contraceptive product may be reduced.

Tell your doctor if you are undergoing any blood or urine tests, because PIPERACILLIN/TAZOBACTAM FRESENIUS may interfere with the results of certain laboratory tests.

Pregnancy and breastfeeding

Do not receive PIPERACILLIN/TAZOBACTAM FRESENIUS if you are pregnant or planning to become pregnant.

Do not receive PIPERACILLIN/TAZOBACTAM FRESENIUS if you are 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 PIPERACILLIN/TAZOBACTAM FRESENIUS.

Driving and using machines

No studies on the effect of ability to drive or use machines have been performed.
It is not always possible to predict to what extent PIPERACILLIN/TAZOBACTAM FRESENIUS 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 PIPERACILLIN/TAZOBACTAM FRESENIUS affects them.

PIPERACILLIN/TAZOBACTAM FRESENIUS contains sodium

PIPERACILLIN/TAZOBACTAM 2 g / 0,25 g FRESENIUS:

This medicine contains 112 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 5,6% of the recommended maximum daily dietary intake of sodium for an adult.

PIPERACILLIN/TAZOBACTAM 4 g / 0,5 g FRESENIUS:

This medicine contains 224 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 11,2% of the recommended maximum daily dietary intake of sodium for an adult.
This should be taken into consideration if you are on a controlled-sodium diet.

3. How to receive PIPERACILLIN/TAZOBACTAM FRESENIUS

PIPERACILLIN/TAZOBACTAM FRESENIUS is for intravenous use only.
You will not be expected to give yourself PIPERACILLIN/TAZOBACTAM FRESENIUS. It will be given to you by a person who is qualified to do so.

Your doctor will decide on the suitable dose and duration of the treatment based on your specific condition and needs.

If you receive more PIPERACILLIN/TAZOBACTAM FRESENIUS than you should

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

If you forget to receive PIPERACILLIN/TAZOBACTAM FRESENIUS

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

4. Possible side effects

PIPERACILLIN/TAZOBACTAM FRESENIUS can have side effects.

Not all side effects reported for PIPERACILLIN/TAZOBACTAM FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving PIPERACILLIN/TAZOBACTAM FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving PIPERACILLIN/TAZOBACTAM FRESENIUS and tell your doctor immediately:

- Serious allergic reactions, including a shock reaction. You may have swelling of the tongue and/or throat, difficulty in swallowing, difficulties in breathing, facial swelling, severe dizziness with a very fast heartbeat and heavy sweating.
- Severe diarrhoea, painful abdominal cramps and nausea with fever and weakness. This is a serious condition for which you may need urgent treatment. Do not use medicines to stop your diarrhoea without talking to your doctor.

- Itching of the vaginal area with a thick, white vaginal discharge (thrush).
- You get more infections than usual. This could be because of a decrease in white blood cells. Your doctor may want to confirm this with a blood test.
- Severe skin reactions. Some signs may be fever, hives (nettle rash), ulcers in the mouth, throat and nose with red and swollen eyes, blistering, peeling or loosening of the top layer of your skin, which may be life-threatening.
- Severe potentially fatal allergic condition (drug reaction with eosinophilia and systemic symptoms) that can involve the skin and most importantly other organs under the skin such as the kidney and the liver.
- Unexpected excessive bleeding, particularly if you also take or receive blood thinning medicines such as warfarin.
- Abnormal breakdown of red blood cells (some signs may be unexpected breathlessness, red or brown urine, nosebleeds and bruising).
- Yellowing of the eyes or skin (your liver may be affected).
- Shivering, reactions at the site of the injection, including fever, reddening of the skin, pain, hardness or swelling.

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

Also tell your doctor if you have any of the following side effects:

Side effects occurring frequently

- Yeast infections (e.g. thrush).
- Nausea (feeling sick), vomiting (being sick), diarrhoea (loose bowels), constipation (difficulty passing stools), stomach pain and heartburn/indigestion.
- Skin rash, itchy skin.
- Reduced levels of platelets or proteins in your blood, bleeding problems.

- Increases in levels of liver enzymes, creatinine or urea in the blood.
- Headache.
- Fever.
- Sleeping problems (insomnia).
- Pain, swelling, warmth or redness around the site of injection.

Side effects occurring less frequently

- Low blood sugar (this will be detected by blood tests in hospital).
- Flushing of the upper body, sudden redness of the face.
- Inflammation of the mouth, sore mouth.
- Joint and muscle pains or weakness in the legs and arms.
- Pale, red, raised and itchy bumps on the skin (urticaria), small red bumps on the skin, peeling of the top layer of the skin.
- Decrease in the number of white blood cells, changes in blood clotting tests.
- Nose bleeds.
- Changes in the number of red or white blood cells, platelets or other components in your blood.
- Iron deficiency (anaemia) or anaemia caused by the breakdown of red blood cells.
- Reduced levels of potassium or glucose in your blood.
- Increased levels of bilirubin in the blood.
- Chest pain.
- Low blood pressure.
- Inflammation of a vein with or without formation of a blood clot.
- Infection of the colon.
- Cold shivers.
- Fever and rash in cystic fibrosis patients.
- Fits (convulsions) seen in patients on high doses or with kidney problems.

Frequency unknown

- Bleeding under the skin, increase in bleeding time.
- Inflammation in the kidney tubes.
- Kidney problems (swelling and problems with urination), inflammation of the kidneys, kidney failure.
- Yellowing of the skin and eyes (jaundice).
- Inflammation of the liver.
- Acute disorientation and confusion (delirium).
- A form of lung disease where eosinophils (a form of white blood cell) appear in the lung in increased numbers.
- Serious body wide allergic reaction with skin and mucous lining rashes, blistering and various skin eruptions (Stevens-Johnson Syndrome), severe allergic condition involving skin and other organs such as the kidney and the liver (drug reaction with eosinophilia and systemic symptoms), numerous tiny fluid filled blisters contained within large areas of swollen and reddened skin accompanied by fever (acute generalised exanthematous pustulosis), skin reactions with blistering (dermatitis bullous).

Laboratory tests can reveal

- A positive antiglobulin test (when the blood is checked to see if it contains certain antibodies).

Some side effects such as temporary blood, kidney or liver problems can only be detected when your doctor orders blood or urine tests to check your progress.

Beta-lactam antibiotics, including piperacillin tazobactam, may lead to signs of altered brain function (encephalopathy) and convulsions.

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 PIPERACILLIN/TAZOBACTAM FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or 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 product is marketed.

5. How to store PIPERACILLIN/TAZOBACTAM FRESENIUS

Store all medicines out of reach of children.

Powder: Store at or below 25 °C.

Keep vial in original container until required for use.

Solutions: Vials containing reconstituted solutions for intravenous and intramuscular use are stable for 2 hours at room temperature (below 25 ºC) and 24 hours under refrigeration (2 – 8 °C).

Discard any unused portion.

Chemical and physical in-use stability has been demonstrated for 2 hours at 25 °C and 24 hours at 2 – 8 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

6. Contents of the pack and other information

What PIPERACILLIN/TAZOBACTAM FRESENIUS contains

The active substances are piperacillin and tazobactam.

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS: Each vial contains piperacillin sodium equivalent to 2 g piperacillin and tazobactam sodium equivalent to 0,25 g tazobactam.

Contains 4,9 mmol (or 112 mg) sodium per vial.

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS: Each vial contains piperacillin sodium equivalent to 4 g piperacillin and tazobactam sodium equivalent to 0,5 g tazobactam.

Contains 9,7 mmol (or 224 mg) sodium per vial.

The other ingredients are glacial acetic acid (for pH-adjustment), sodium bicarbonate (for pH-adjustment) and water for injection. All these ingredients are removed during manufacture and therefore do not appear in the finished product.

Sugar free.

What PIPERACILLIN/TAZOBACTAM FRESENIUS looks like and contents of the pack:

White or almost white hygroscopic powder.

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS: packed in a clear 50 mL Type II glass vial with a grey 32 mm chlorobutyl rubber stopper sealed with an aluminium cap with a blue polypropylene flip-off lid or a clear 15 mL Type II glass vial with a grey 20 mm chlorobutyl rubber stopper sealed with an aluminium cap with a blue polypropylene flip-off lid.

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS: a clear 50 mL Type II glass vial with a grey 32 mm chlorobutyl rubber stopper sealed with an aluminium cap with a red polypropylene flip-off lid.

Pack sizes: 1, 5, 10 or 12 vials in an outer carton.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Ltd

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162 Tonetti Street

Halfway House extension 7

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1685

SOUTH AFRICA

Telephone number: (011) 545 0000

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Registration number(s)

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS: 45/20.1.1/1172

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS: 45/20.1.1/1173

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS

Poeier vir oplossing vir infusie

Piperasillien

Tasobaktaam

Suikervry

Lees die hele inligtingsblad aandagtig deur voordat PIPERACILLIN/TAZOBACTAM 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

7. Wat is PIPERACILLIN/TAZOBACTAM FRESENIUS en waarvoor word dit gebruik
8. Wat jy moet weet voordat PIPERACILLIN/TAZOBACTAM FRESENIUS aan jou gegee word
9. Hoe PIPERACILLIN/TAZOBACTAM FRESENIUS aan jou gegee sal word
10. Moontlike newe-effekte
11. Hoe om PIPERACILLIN/TAZOBACTAM FRESENIUS te bewaar
12. Inhoud van die pakkie en ander inligting.

1. Wat is PIPERACILLIN/TAZOBACTAM FRESENIUS en waarvoor word dit gebruik

PIPERACILLIN/TAZOBACTAM FRESENIUS word gebruik vir die behandeling van matig-tot-ernstige infeksies veroorsaak deur sekere bakterieë.
PIPERACILLIN/TAZOBACTAM FRESENIUS is 'n antibakteriële geneesmiddel. Dit blokkeer die groei van bakteriële selwande en dood so die bakterieë.

2. Wat jy moet weet voordat PIPERACILLIN/TAZOBACTAM FRESENIUS aan jou gegee word

PIPERACILLIN/TAZOBACTAM FRESENIUS moet nie aan jou gegee word nie:

- indien jy allergies (hipersensitief) is vir piperasillien of tasobaktaam of enige van die bestanddele van PIPERACILLIN/TAZOBACTAM FRESENIUS (gelys in afdeling 6).
- indien jy allergies is vir penisillien- of kefalasporienantibiotika, of vir medisyne genaamd beta-laktaamantibiotika inhibitore.
- PIPERACILLIN/TAZOBACTAM FRESENIUS is nie vir kinders onder 2 jaar oud aangedui nie.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat jy ingespuit word:

Wees veral versigtig vir PIPERACILLIN/TAZOBACTAM FRESENIUS:

- indien jy oor die algemeen allergies is vir sommige medisyne en/of voedselsoorte, aangesien ernstige of selfs noodlottige allergiese reaksies met PIPERACILLIN/TAZOBACTAM FRESENIUS voorgekom het
- indien jy diarree ondervind na aanvang van behandeling met PIPERACILLIN/TAZOBACTAM FRESENIUS. Kontak dadelik jou dokter, aangesien jy moontlik die behandeling sal moet staak
- indien jy weet dat jy sekere bloedafwykings het, soos 'n verlengde stollingstyd en 'n lae witbloedseltelling. Langdurige behandeling met PIPERACILLINE/TAZOBACTAM FRESENIUS kan lei tot 'n afname in die aantal witbloedselle en 'n groter kans op 'n infeksie

- indien jy weet dat jy lae bloedkaliumvlakke het. Jou dokter wil dalk eers jou niere ondersoek en gereelde bloedtoetse tydens behandeling doen
- indien jy kankerbehandeling kry
- indien jy diuretika neem (ontwateringstablette vir hartprobleme of hoë bloeddruk)
- indien jy medisyne soos heparien of warfarien neem of gebruik om bloedklonte te voorkom (sien "**Ander medisyne en PIPERACILLIN/TAZOBACTAM FRESENIUS**")
- indien jy 'n ander antibiotikum, genaamd vankomisien saam met PIPERACILLIN/TAZOBACTAM FRESENIUS neem, kan dit die risiko van nierskade verhoog (sien ook "**Ander medisyne en PIPERACILLIN/TAZOBACTAM FRESENIUS**")
- indien jy in die verlede aan stuiptrekkings of aanvalle gely het, aangesien dit 'n aanval kan veroorsaak
- indien jy 'n niersiekte het of as jy hemodialise ontvang. Jou dokter wil dalk eers jou niere ondersoek en mag gereelde bloedtoetse tydens die behandeling doen
- indien jy lewerprobleme het.

Jy moet ook weet dat:

PIPERACILLIN/TAZOBACTAM FRESENIUS ernstige velreaksies kan veroorsaak, soos 'n rooi vel met blaasvorming, vervelling of loslating van die boonste vellaag, wat lewensgevaarlik kan wees. (Kyk afdeling 4).

By hoë dosisse PIPERACILLIN/TAZOBACTAM FRESENIUS kan senuweestelselkomplikasies soos konvulsies voorkom, veral as jou niere nie behoorlik werk nie. (Sien afdeling 4)

Daar is berigte van 'n siekte waarby die immuunstelsel te veel andersins normale witbloedselle genaamd histiosiete en limfosiete vervaardig, wat lei tot inflammasie (hemofagositiese limfohistiositose). Hierdie siektetoestand kan lewensgevaarlik wees indien

dit nie vroegtydig gediagnoseer en behandel word nie. Indien jy veelvuldige simptome ervaar soos koors, geswelde kliere, swakheid, lighoofdigheid, kortasem, kneusplekke of veluitslag, kontak dadelik jou dokter.

Ander medisyne en PIPERACILLIN/TAZOBACTAM FRESENIUS

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem.
(Dit sluit alle komplementêre of tradisionele medisyne in.)

Sê vir jou dokter as jy die volgende neem:

- Ander antibiotika soos tetrasiklien, chlooramfenikol, vankomisien, tobramisien.
  Lig jou dokter in as jy nierprobleme het. Die gelyktydige gebruik van PIPERACILLIN/TAZOBACTAM FRESENIUS en vankomisien kan die risiko van nierskade verhoog, selfs al het jy geen nierprobleme nie.
- Probenesied (gebruik vir jig).
- Warfarien of ander medisyne om jou bloed te verdun.
- Nie-steroïdale anti-inflammatoriese geneesmiddels (NSAIG's) soos ibuprofeen.
- Vekuronium (spierverslapper, gebruik by operasies).
- Metotreksaat (kan by kankerterapie gebruik word).
- Mondelike voorbehoedmiddels, aangesien die doeltreffendheid van die mondelike voorbehoedmiddel verminder kan word.

Lig jou dokter in as jy enige bloed- of urientoetse ondergaan, want PIPERACILLIN/TAZOBACTAM FRESENIUS kan die resultate van sekere laboratoriumtoetse beïnvloed.

Swangerskap en borsvoeding

Moet nie PIPERACILLIN/TAZOBACTAM FRESENIUS ontvang indien jy swanger is, of beplan om swanger te raak nie.
Moet nie PIPERACILLIN/TAZOBACTAM FRESENIUS ontvang indien jy borsvoed nie.

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 PIPERACILLIN/TAZOBACTAM FRESENIUS ontvang.

Bestuur en die gebruik van masjinerie

Geen studies is gedoen oor die uitwerking op die vermoë om te bestuur en masjiene te gebruik nie.

Dit is nie altyd moontlik om te voorspel tot watter mate PIPERACILLIN/TAZOBACTAM FRESENIUS 'n pasiënt se daaglikse aktiwiteite kan beïnvloed nie. Pasiënte moet sorg dat hulle nie die bogenoemde aktiwiteite uitvoer nie totdat hulle weet hoe PIPERACILLIN/TAZOBACTAM FRESENIUS hulle beïnvloed.

PIPERACILLIN/TAZOBACTAM FRESENIUS bevat natrium

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS:

Hierdie medisyne bevat 112 mg natrium (hoofkomponent van kook/tafelsout) in elke flessie. Dit is gelykstaande aan 5,6 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

PIPERACILLIN/TAZOBACTAM 4 g/0,25 g FRESENIUS:

Hierdie medisyne bevat 224 mg natrium (hoofkomponent van kook/tafelsout) in elke flessie. Dit is gelykstaande aan 11,2 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

Dit moet in ag geneem word indien jy 'n natriumbeheerde dieet volg.

3. Hoe PIPERACILLIN/TAZOBACTAM FRESENIUS aan jou gegee sal word

PIPERACILLIN/TAZOBACTAM FRESENIUS is slegs vir intraveneuse gebruik.

Daar sal nie van jou verwag word om PIPERACILLIN/TAZOBACTAM 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 op grond van jou spesifieke siektetoestand en behoeftes besluit oor 'n geskikte dosis en duur van die behandeling.

Indien jy meer PIPERACILLIN/TAZOBACTAM FRESENIUS ontvang het as wat jy moes
Aangesien 'n gesondheidsorgverskaffer PIPERACILLIN/TAZOBACTAM 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 PIPERACILLIN/TAZOBACTAM FRESENIUS te gebruik
Aangesien 'n gesondheidsorgverskaffer PIPERACILLIN/TAZOBACTAM FRESENIUS sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte

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

Indien enige van die volgende gebeur, hou op om PIPERACILLIN/TAZOBACTAM FRESENIUS te ontvang en lig jou dokter dadelik in:

- Ernstige allergiese reaksies, wat 'n skok-reaksie insluit. Jy kan die volgende ervaar: 'n geswelde tong en/of keel, sukkel om te sluk of asem te haal, swelling van die gesig, erge duiseligheid met 'n baie vinnige hartklop en baie sweet.

- Erge diarree, pynlike buikkrampe en naarheid met koors en swakheid. Dit is 'n ernstige toestand waarvoor jy dringend behandeling kan benodig. Moet nie medisyne gebruik om jou diarree te stop sonder dat jy met jou dokter praat nie.
- Jeuk van die vaginale area met 'n dik, wit vaginale afskeiding (sproei).
- Indien jy meer infeksies as gewoonlik kry. Dit kan wees vanweë 'n afname in witbloedselle. Jou dokter sal dit dalk met 'n bloedtoets wil bevestig.
- Erge velreaksies. Tekens kan insluit koors, netelroos, sere in die mond, keel en neus met rooi en geswolle oë, blase, afskilfering of vervelling van die boonste laag vel, wat lewensgevaarlik kan wees.
- Erge potensieel dodelike allergiese toestand (geneesmiddelreaksie met eosinofilie en sistemiese simptome) wat die vel en veral ander organe onder die vel, soos die niere en lewer, kan aantas.
- Onverwagte buitensporige bloeding, veral indien jy ook bloedverdunnende medisyne soos warfarien neem of gebruik.
- Abnormale afbraak van rooibloedselle (sommige tekens kan wees: onverwagte kortasemheid, rooi of bruin urien, neusbloeding en kneusplekke).
- Geel verkleuring van die oë of vel (jou lewer kan aangetas wees).
- Bewing, reaksies by die plek van inspuiting, insluitend koors, rooiheid van die vel, pyn, hardheid of swelling.

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

Lig jou dokter ook in as jy enige van die volgende newe-effekte waarneem:

Newe-effekte wat gereeld voorkom

- Gisinfeksies (bv. sproei).

- Naarheid (mislike gevoel), braking (opgooi), diarree (los stoelgange), hardlywigheid (sukkel om stoelgange te passeer), maagpyn en sooibrand/slegte spysvertering.
- Veluitslag, jeukende vel.
- Verminderde hoeveelheid bloedplaatjies of proteïne in jou bloed, bloedingsprobleme.
- Verhoging van die vlakke van lewerensieme, kreatinien of ureum in die bloed.
- Hoofpyn.
- Koors.
- Slaapprobleme (slapeloosheid).
- Pyn, swelling, warmte of rooiheid om die plek van inspuiting.

Newe-effekte wat minder gereeld voorkom

- Lae bloedsuiker (dit sal deur bloedtoetse in die hospitaal opgespoor word).
- Gloede in die bolyf, skielike rooiheid in die gesig.
- Inflammasie van die mond, seer mond.
- Gewrigs- en spierpyne of swakheid in die bene en arms.
- Bleek, rooi, verhewe en jeukende knoppe op die vel (urtikarie), klein rooi knoppies op die vel, afskilfering van die boonste vellaag.
- Afname in die aantal witbloedselle, veranderinge in bloedstollingstoetse.
- Neusbloeding.
- Veranderinge in die aantal rooi- of witbloedselle, bloedplaatjies of ander komponente in jou bloed.
- Ystertekort (bloedarmoede) of bloedarmoede veroorsaak deur die afbraak van rooibloedselle.
- Verlaagde kalium- of glukosevlakke in jou bloed.
- Verhoogde bilirubienvlakke in die bloed.
- Borspyn.
- Lae bloeddruk.

- Inflammasie van 'n aar, met of sonder die vorming van 'n bloedklont.
- Infeksie van die kolon.
- Koue rillings.
- Koors en uitslag by pasiënte met sistiese fibrose.
- Stuipe (konvulsies), gesien by pasiënte op hoë dosisse of met nierprobleme.

Frekwensie onbekend

- Bloeding onder die vel, toename in bloedingstyd.
- Inflammasie van die nierbuisies.
- Nierprobleme (swelling en probleme met urinering), inflammasie van die niere, nierversaking.
- Geel verkleuring van die vel en oë (geelsug).
- Ontsteking van die lewer.
- Akute disoriëntasie en verwarring (delirium).
- 'n Vorm van longsiekte waar eosinofiele (’n vorm van witbloedselle) in verhoogde getalle in die longe voorkom.
- Ernstige allergiese reaksie wat die hele liggaam aantas met 'n uitslag op die vel en slymvliese, blaasvorming en verskeie tipes veluitslag (Stevens-Johnson-sindroom), erge allergiese toestand wat die vel en ander organe soos die niere en lewer betrek (geneesmiddelreaksie met eosinofilie en sistemiese simptome), talle klein vloeistofgevulde blase in groot areas van geswolle en rooi vel, gepaardgaande met koors (akute veralgemeende eksanteemagtige pustulose), velreaksies met blaasvorming (bulleuse dermatitis).

Laboratoriumtoetse kan openbaar

- 'n Positiewe antiglobulientoets (wanneer die bloed getoets word om te sien of dit sekere teenliggaampies bevat).

Sommige newe-effekte soos tydelike bloed-, nier- of lewerprobleme kan slegs opgespoor word wanneer jou dokter bloed- of urientoetse aanvra om jou vordering te bepaal.

Beta-laktaamantibiotika, insluitend piperasillien-tasobaktaam, kan lei tot tekens van veranderde breinfunksie (ensefalopatie) en konvulsies.

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 PIPERACILLIN/TAZOBACTAM FRESENIUS te verskaf.

Pasiënte word versoek 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 PIPERACILLIN/TAZOBACTAM FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Poeier: Berg by of benede 25 °C.

Bêre die flessie in die oorspronklike houer totdat dit benodig word vir gebruik.

Oplossings: Flessies wat hersaamgestelde oplossings vir intraveneuse en binnespierse gebruik bevat, is stabiel vir 2 uur by kamertemperatuur (onder 25 ºC) en 24 uur onder verkoeling (2 – 8 °C).

Gooi enige ongebruikte gedeelte weg.

Chemiese en fisiese stabiliteit tydens gebruik is aangetoon vir 2 uur by 25 °C en 24 uur by 2 – 8 °C. Vanuit 'n mikrobiologiese oogpunt moet die produk onmiddellik gebruik word. Indien dit nie onmiddellik gebruik word nie, is dit die gebruiker se verantwoordelikheid vir die bergingstye en -toestande voor gebruik; dit moet normaalweg nie langer as 24 uur by 2 tot 8 °C wees nie, tensy hersamestelling /verdunning onder beheerde en gevalideerde aseptiese toestande plaasgevind het.

6. Inhoud van die pakkie en ander inligting

Wat PIPERACILLIN/TAZOBACTAM FRESENIUS bevat

Die aktiewe bestanddele is piperasillien en tasobaktaam.

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS: Elke flessie bevat natriumpiperasillien gelykstaande aan 2 g piperasillien en natriumtasobaktaam gelykstaande aan 0,25 g tasobaktaam.

Bevat 4,9 mmol (of 112 mg) natrium per flessie.

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS: Elke flessie bevat natriumpiperasillien gelykstaande aan 4 g piperasillien en natriumtasobaktaam gelykstaande aan 0,5 g tasobaktaam.

Bevat 9,7 mmol (of 224 mg) natrium per flessie.

Die ander bestanddele is ysasynsuur (vir pH-aanpassing), natriumbikarbonaat (vir pH-aanpassing) en water vir inspuiting. Al hierdie bestanddele word tydens vervaardiging verwyder en kom dus nie in die finale produk voor nie.

Suikervry.

Hoe PIPERACILLIN/TAZOBACTAM FRESENIUS lyk en inhoud van die pakkie:

Wit tot amperwit higroskopiese poeier.

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS: verpak in 'n 50 mL deursigtige Tipe II-glasflessie met 'n grys 32 mm chloorbutielrubberprop, verseël met 'n aluminiumdop met 'n blou polipropileen-afklapdop of 'n 15 mL deursigtige Tipe II-glasflessie met 'n grys 20 mm chloorbutielrubberprop, verseël met 'n aluminiumdop met 'n blou polipropileen-afklapdop.

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS: 'n Deursigtige 50 mL Tipe II-glasflessie met 'n grys 32 mm chloorbutielrubberprop verseël met 'n aluminiumdop met 'n rooi polipropileen-afklapdop.

Verpakkingsgroottes: 1, 5, 10 of 12 flessies in 'n buitekarton.

Nie alle pakke of verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat

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Hierdie inligtingsblad is voorheen hersien in

27 Mei 2025

Registrasienommer(s)

PIPERACILLIN/TAZOBACTAM 2 g/0,25 g FRESENIUS: 45/20.1.1/1172

PIPERACILLIN/TAZOBACTAM 4 g/0,5 g FRESENIUS: 45/20.1.1/1173

Toegang tot die ooreenstemmende Professionele Inligting

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