PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AMPICILLIN 250 mg FRESENIUS (powder for solution for injection/infusion)

AMPICILLIN 500 mg FRESENIUS (powder for solution for injection/infusion)

Ampicillin sodium

Sugar free

Read all of this leaflet carefully before you are given AMPICILLIN 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 AMPICILLIN FRESENIUS is and what it is used for
2. What you need to know before you are given AMPICILLIN FRESENIUS
3. How AMPICILLIN FRESENIUS is given to you
4. Possible side effects
5. How to store AMPICILLIN FRESENIUS
6. Contents of the pack and other information

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

The active substance is ampicillin sodium.

Ampicillin is a penicillin type of antibiotic. Ampicillin can kill certain bacteria which cause infections.

AMPICILLIN FRESENIUS is used for the treatment of certain infections caused by sensitive organisms.

2. What you need to know before you are given AMPICILLIN FRESENIUS

AMPICILLIN FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to ampicillin, other penicillins or any other antibiotics, such as cephalosporins otherwise also known as beta-lactam antibiotics.
- in new-born babies whose mothers are allergic to penicillin.
- in the eye

Warnings and precautions

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

If you have a history of other allergies;

Tell your doctor if you are allergic to penicillins, cephalosporins, any other medications, or have a history of allergy. Serious and sometimes fatal allergic reactions are more likely to occur in patients with a history of penicillin allergy or other allergies.

Your healthcare professional should observe you for at least one hour after you have been administered AMPICILLIN FRESENIUS**.**

AMPICILLIN FRESNIUS should be stopped and emergency help given if you have any of these signs of a severe allergic reaction: difficulty breathing; swelling of your face, lips, tongue or throat.

- if you have infectious mononucleosis (also known as mono, an infection most commonly caused by the Epstein–Barr virus) - see Possible side effects;
- if you have HIV infection;
- if you have lymphatic leukaemia (a type of cancer of the blood and bone marrow) or neutropenia (a low number of certain white blood cells);
- if you are treated for syphilis – see the Jarisch-Herxheimer adverse reaction under Possible side effects;

- if you have persistent diarrhoea - see Possible side effects;
- if you have kidney problems;
- if you have heart problems;
- if you have liver problems such as hepatitis or jaundice;
- if you are on a low sodium (salt) diet;
- if you have a bleeding or blood clotting disorder;
- if a skin rash occurs, AMPICILLIN FRESENIUS injection should be stopped;
- A serious form of diarrhoea (pseudomembranous colitis) may develop if you use AMPICILLIN FRESENIUS for a long period of time. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur;
- During long-term treatment, your doctor may want to take routine blood tests to monitor your kidney function, liver function and levels of blood cells;
- Following long-term treatment, numbness, tingling, pins and needles has rarely been reported;
- AMPICILLIN FRESENIUS can cause interference in some tests for glucose in urine. Penicillins which are excreted in urine can cause a false-positive result. Your doctor will request a test which is not affected by penicillins;
- AMPICILLIN FRESENIUS may interfere with certain laboratory tests. Be sure your doctor and laboratory personnel know you are using AMPICILLIN FRESENIUS**;**
- If you are receiving high doses, make sure that you take enough fluids;
- Lignocaine (lidocaine) and benzyl alcohol should only be used together with AMPICILLIN FRESENIUS when AMPICILLIN FRESENIUS is injected into a muscle, and must not be given into a vein.

Other medicines and AMPICILLIN 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 any of the following medicines:

- Allopurinol (a medicine used for gout)-There is an increased possibility of skin rashes occurring in patients taking AMPICILLIN FRESENIUS together with allopurinol;
- Antibiotics (aminoglycosides such as gentamycin)-There is an increased possibility of substantial inactivation of the aminoglycoside in patients receiving AMPICILLIN FRESENIUS together with the aminoglycoside;
- Antibiotics (beta-lactams such as cephalosporins)-There is an increased possibility of substantial mutual inactivation of both the aminoglycoside and AMPICILLIN FRESENIUS when administered concurrently in the same syringe;
- Oral contraceptives containing oestrogens; AMPICILLIN FRESENIUS may decrease the effectiveness of birth control pills. Use an alternative or additional method of birth control while taking AMPICILLIN FRESENIUS to protect against pregnancy;
- Methotrexate for the treatment of certain cancers. AMPICILLIN FRESENIUS may decrease the removal of methotrexate from the body, increasing the risk of its side effects. Your doctor may want to monitor the amount of methotrexate in your blood if you are receiving methotrexate treatment in combination with AMPICILLIN FRESENIUS. Leucovorin doses may need to be increased and administered for longer periods of time;
- NSAIDs (non-steroidal anti-inflammatory drugs) or salicylates (e.g. aspirin) – The risk of bleeding is increased when these medicines are used together with AMPICILLIN FRESENIUS**;**
- ACE inhibitors, potassium-sparing diuretics, potassium containing medicines or potassium supplements- Use of these medicines together with AMPICILLIN FRESENIUS may cause too much potassium in the blood, especially in patients with kidney problems;
- Anticoagulant treatment used to prevent blood clots (warfarin), when used in combination with AMPICILLIN FRESENIUS may increase the risk of haemorrhage.

If your blood is drawn for laboratory tests, inform the healthcare provider that you have received AMPICILLIN FRESENIUS, as it may affect the outcome of some tests, such as the antiglobulin (Coombs') test and some urinary sugar tests.

AMPICILLIN FRESENIUS with food and drink and alcohol

It is recommended that alcohol should be avoided during and for several days after treatment with AMPICILLIN FRESENIUS**.**

Pregnancy and 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 receiving AMPICILLIN FRESENIUS**.**

- Safety in pregnancy and breastfeeding has not been established.
- AMPICILLIN FRESENIUS pass into breast milk. The use of AMPICILLIN FRESENIUS by breastfeeding mothers may cause sensitivity (allergic reaction) such as diarrhoea, thrush and skin rash in the baby.

Driving and using machines

It is not always possible to predict to what extent AMPICILLIN 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 AMPICILLIN FRESENIUS affects them.

3. How is AMPICILLIN FRESENIUS given to you

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

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

You will receive AMPICILLIN FRESENIUS by injection into a muscle (intramuscularly) or into a vein (intravenously).

If you have the impression that the effect of AMPICILLIN FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

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

If you receive more AMPICILLIN FRESENIUS than you should

Since a healthcare provider will administer AMPICILLIN FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. Overdose symptoms are usually asymptomatic but may include increased gastrointestinal side effects such as nausea, vomiting and diarrhoea.

If you have not received a dose of AMPICILLIN FRESENIUS

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

4. Possible side effects

AMPICILLIN FRESENIUS can have side effects.

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

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

- swelling or the tongue, lips or throat, difficulty breathing or tightness of the chest;
- skin rash, red skin with fever and aching joints, peeling of skin, hives or itchy skin;
- fever, chills, headaches, reactions at the site of the lesion, problems with vision (known as the Jarisch-Herxheimer reaction) that may occur if you are treated with medicines for syphilis;
- severe and persistent watery diarrhoea with cramps and fever;
- yellowing of the skin and eyes (jaundice);
- urinating less than usual or not at all.

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

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

- pain on the kidney with difficult urination and blood in the urine (interstitial nephritis);
- thrush or infections with other germs (you may feel feverish and tired);
- fits (convulsions);
- if you notice after an injury or a nose bleed that your blood does not clot as quickly as before;
- pain or bruising at the injection site, muscle and joint pain;
- crystals found in the urine.

Laboratory tests can reveal: A positive Coomb's test (antiglobulin test), increased liver enzyme values, changes in sodium and potassium levels.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea (feeling sick)
- vomiting
- diarrhoea

Less frequent side effects:

- anaemia (tiredness, being short of breath and looking pale);
- skin rash, red skin with fever and aching joints, peeling of skin, hives or itchy skin;
- too few white blood cells (sore throat and fever);
- numbness, tingling, pins and needles;
- thrush (white patches inside your mouth or throat, vaginal itching or discharge);
- increased muscular activity;
- dizziness; nausea (queasiness, feeling that one is about to vomit);
- inflammation of the mouth; inflammation of the tongue; black hairy tongue;

- heartburn;
- inflammation of the blood vessels,

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AMPICILLIN 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 product is marketed.

5. How to store AMPICILLIN FRESENIUS

Store all medicines out of reach of children.

Store at or below 30 °C in a dry place.

Return all unused medicine to your pharmacist.

Do not freeze.

Protect from light.

Do not dispose of unused medicine in the drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AMPICILLIN FRESENIUS contains

Vials of sterile white powder containing 250 mg or 500 mg ampicillin as ampicillin sodium.

What AMPICILLIN FRESENIUS looks like and contents of the pack

AMPICILLIN FRESENIUS is a sterile soluble white powder in a sealed vial.

Packed in containers of 10 and 100.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House extension 7

Midrand

Gauteng

1685

Telephone number: (011) 545 0000

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Registration number(s)

AMPICILLIN 250 mg FRESENIUS: H/20.1.2/25

AMPICILLIN 500 mg FRESENIUS: H/20.1.2/26

Access to the corresponding Professional Information

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

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

AMPICILLIN 250 mg FRESENIUS (poeier vir oplossing vir inspuiting/infusie)

AMPICILLIN 500 mg FRESENIUS (poeier vir oplossing vir inspuiting/infusie)

Natriumampisillien

Suikervry

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

- Hou hierdie inligtingsblad. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad

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

1. Wat is AMPICILLIN FRESENIUS en waarvoor word dit gebruik

Die aktiewe bestanddeel is natriumampisillien.

Ampisillien is 'n penisillien-tipe antibiotikum. Ampisillien kan sekere bakterieë wat infeksies veroorsaak doodmaak.

AMPICILLIN FRESENIUS word gebruik vir die behandeling van sekere infeksies wat deur gevoelige organismes veroorsaak word.

2. Wat jy moet weet voordat AMPICILLIN FRESENIUS aan jou gegee word

AMPICILLIN FRESENIUS moet nie aan jou toegedien word nie

- indien jy hipersensitief (allergies) is vir ampisillien, ander penisilliene of enige ander antibiotika soos kefalosporiene, ook bekend as beta-laktaamantibiotika.
- in pasgebore babas wie se moeders allergies is vir penisillien.
- in die oog.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting/infusie aan jou gegee word:

Indien jy ’n geskiedenis het van allergieë;

Lig jou dokter in as jy allergies is vir penisilliene, kefalosporiene of ander medikasies of 'n geskiedenis van allergie het. Ernstige en soms dodelike allergiese reaksies is meer algemeen in pasiënte met 'n geskiedenis van penisillien-allergie of ander allergieë.

Jou gesondheidsorgkundige moet jou vir ten minste een uur na toediening van AMPICILLIN FRESENIUS waarneem**.**

AMPICILLIN FRESNIUS moet gestop word en noodhulp gegee word as jy enige van hierdie tekens van 'n ernstige allergiese reaksie ervaar: moeilike asemhaling; swelling van die gesig, lippe, tong of keel.

- indien jy aansteeklike mononukleose het (ook bekend as mono, 'n infeksie wat hoofsaaklik deur die Epstein-Barr-virus veroorsaak word) - sien Moontlike newe-effekte
- indien jy MIV-infeksie het;
- indien jy limfatiese leukemie ('n vorm van bloed- en beenmurgkanker) of neutropenie ('n lae aantal van sekere witbloedselle) het;
- indien jy vir sifilis behandel word – sien die Jarisch-Herxheimer ongunstige reaksie onder

Moontlike newe-effekte;

- indien jy volgehoue diarree het - sien Moontlike newe-effekte;
- indien jy nierprobleme het;
- indien jy hartprobleme het;
- indien jy lewerprobleme het, soos hepatitis of geelsug;
- indien jy op 'n lae-natrium (sout) dieet is;
- indien jy 'n bloeding- of bloedstollingsversteuring het;
- indien 'n veluitslag voorkom, moet inspuiting van AMPICILLIN FRESENIUS gestaak word;
- 'n Ernstige vorm van diarree (pseudomembraneuse kolitis) kan met langdurige gebruik van AMPICILLIN FRESENIUS ontwikkel. Kontak dadelik jou dokter as maagpyn of krampe, erge diarree of bloederige stoelgang voorkom;
- Met langtermynbehandeling kan jou dokter roetine-bloedtoetse doen om jou nierfunksie, lewerfunksie en bloedselvlakke te kontroleer;
- Gevoelloosheid, tinteling of speld-en-naaldprikkels is selde na langtermynbehandeling aangemeld.
- AMPICILLIN FRESENIUS kan sommige urienglukosetoetse beïnvloed. Penisilliene wat in urien uitgeskei word, kan 'n vals-positiewe resultaat veroorsaak. Jou dokter sal 'n toets aanvra wat nie deur penisilliene aangetas sal word nie;
- AMPICILLIN FRESENIUS kan sekere laboratoriumtoetse beïnvloed. Maak seker jou dokter en laboratoriumpersoneel weet dat jy AMPICILLIN FRESENIUS gebruik;
- Indien jy hoë dosisse ontvang, sorg dat jy genoeg vloeistowwe inneem;
- Lignokaïen (lidokaïen) en bensielalkohol moet slegs saam met AMPICILLIN FRESENIUS gebruik word wanneer AMPICILLIN FRESENIUS in 'n spier ingespuit word, en moet nie in 'n aar toegedien word nie.

Ander medisyne en AMPICILLIN FRESENIUS

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

Lig jou dokter in as jy enige van die volgende medisyne neem:

- Allopurinol ('n medisyne teen jig) - Pasiënte wat AMPICILLIN FRESENIUS saam met allopurinol neem, loop 'n groter risiko om veluitslag te ontwikkel;
- Antibiotika (aminoglikosiede soos gentamisien) - Pasiënte wat AMPICILLIN FRESENIUS saam met 'n aminoglikosied ontvang, het 'n groter kans op beduidende inaktivering van die aminoglikosied;
- Antibiotika (beta-laktame soos kefalosporiene) - Daar is 'n groter moontlikheid van beduidende wedersydse inaktivering van beide die aminoglikosied en AMPICILLIN FRESENIUS wanneer dit gelyktydig in dieselfde spuit toegedien word;
- Orale voorbehoedmiddels wat estrogene bevat; AMPICILLIN FRESENIUS kan die doeltreffendheid van geboortebeperkingspille verminder. Gebruik 'n alternatiewe of bykomende metode van voorbehoeding om swangerskap te voorkom terwyl jy AMPICILLIN FRESENIUS ontvang;
- Metotreksaat vir die behandeling van sekere kankers. AMPICILLIN FRESENIUS kan die opruiming van metotreksaat uit die liggaam verminder, wat die risiko van newe-effekte verhoog. Jou dokter sal dalk die hoeveelheid metotreksaat in jou bloed wil monitor as jy metotreksaatbehandeling in kombinasie met AMPICILLIN FRESENIUS ontvang. Die leukovorien-dosis moet dalk verhoog en vir 'n langer tydperk toegedien word;
- NSAIM's (nie-steroïdale anti-inflammatoriese middels) of salisilate (bv. aspirien) - Die risiko van bloeding word verhoog wanneer hierdie middels saam met AMPICILLIN FRESENIUS gebruik word;
- AOE-inhibitore, kaliumbesparende diuretika, kaliumbevattende medisyne of kaliumaanvullings- Gebruik van hierdie medisyne saam met AMPICILLIN FRESENIUS kan te veel kalium in die bloed veroorsaak, veral in pasiënte met nierprobleme;
- Antistollingsbehandeling om bloedklonte te voorkom (warfarien), gebruik in kombinasie met AMPICILLIN FRESENIUS kan die risiko van bloeding verhoog.

Indien jou bloed vir laboratoriumtoetse getrek word, moet jy die gesondheidsorgverskaffer inlig dat jy AMPICILLIN FRESENIUS ontvang het, aangesien dit die uitslag van sommige

toetse, soos die antiglobulien (Coomb's) toets en sommige uriensuikertoetse kan beïnvloed.

AMPICILLIN FRESENIUS met kos en vloeistowwe en alkohol

Dit word aanbeveel dat alkohol vermy word tydens en vir 'n paar dae na behandeling met AMPICILLIN FRESENIUS.

Swangerskap en borsvoeding en vrugbaarheid

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 AMPICILLIN FRESENIUS ontvang**.**

- Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.
- AMPICILLIN FRESENIUS kom in borsmelk voor. Die gebruik van AMPICILLIN FRESENIUS deur moeders wat borsvoed kan gevoeligheid (allergiese reaksie) soos diarree, sproei en veluitslag in die baba veroorsaak.

Bestuur en die gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel tot watter mate AMPICILLIN FRESENIUS die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak voordat hulle bewus is van die mate waartoe AMPICILLIN FRESENIUS hulle beïnvloed nie.

3. Hoe AMPICILLIN FRESENIUS aan jou gegee sal word

Moet nie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Jou dokter sal jou inlig hoe lank jou behandeling met AMPICILLIN FRESENIUS sal duur.
Jy sal AMPICILLIN FRESENIUS ontvang deur inspuiting in 'n spier (intramuskulêr) of in 'n aar (intraveneus).
Indien jy die indruk kry dat die effek van AMPICILLIN FRESENIUS te sterk of te swak is, lig jou dokter of apteker in.

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

Indien jy meer AMPICILLIN FRESENIUS ontvang as wat jy moet

Aangesien 'n gesondheidsorgverskaffer AMPICILLIN FRESENIUS sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel. Simptome van oordosis is gewoonlik asimptomaties, maar kan verhoogde gastroïntestinale newe-effekte insluit soos naarheid, braking en diarree.

Indien jy 'n dosis van AMPICILLIN FRESENIUS oorgeslaan het

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

4. Moontlike newe-effekte

AMPICILLIN FRESENIUS kan newe-effekte hê.

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

Indien enige van die volgende gebeur, hou op om AMPICILLIN FRESENIUS te gebruik en lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal

- swelling van die tong, lippe of keel, moeilike asemhaling of benoudheid van die bors;
- veluitslag, rooi vel met koors en pynlike gewrigte, vel dop af, netelroos of jeukerige vel;
- koors, kouekoors, hoofpyne, reaksies by die plek van die letsel, probleme met visie (bekend as die Jarisch-Herxheimer-reaksie) wat kan voorkom as jy met medisyne vir sifilis behandel word;
- erge en volgehoue waterige diarree met krampe en koors;
- geel verkleuring van die vel en oë (geelsug);

- urineer minder as gewoonlik of glad nie.

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik 'n ernstige reaksie op AMPICILLIN FRESENIUS hê. Jy kan dringende mediese aandag benodig.

Lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

- pyn op die nier met moeilike urinering en bloed in die uriene (interstisiële nefritis);
- sproei of infeksies met ander kieme (jy kan koorsig en moeg voel);
- toevalle (konvulsies);
- indien jy ná ’n besering of ’n neusbloeding agterkom dat jou bloed nie so vinnig soos voorheen stol nie;
- pyn of kneusing by die plek van inspuiting, spier en gewrigspyn;
- kristalle in die uriene.

Laboratoriumtoetse kan onthul:’n Positiewe Coomb’s-toets (antiglobulientoets), verhoogde lewerensiemwaardes, veranderinge in natrium- en kaliumvlakke.

Al hierdie newe-effekte is ernstig. Jy kan dringende mediese aandag benodig.
Lig jou dokter in as jy enige van die volgende waarneem:

Gereelde newe-effekte:

- naarheid (mislike gevoel)
- braking
- diarree

Minder gereelde newe-effekte:

- anemie (moegheid, kort van asem en bleek voorkoms);
- veluitslag, rooi vel met koors en pynlike gewrigte, vel dop af, netelroos of jeukerige vel;
- te min witbloedselle (seerkeel en koors);

- gevoelloosheid, tinteling, speld-en-naaldprikkels;
- sproei (wit kolle in jou mond of keel, vaginale jeuking of afskeiding);
- verhoogde spieraktiwiteit;
- duiseligheid; naarheid (mislikheid, gevoel asof jy gaan opgooi);
- inflammasie van die mond; inflammasie van die tong; swart harige tong;
- sooibrand;
- inflammasie van die bloedvate.

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 AMPICILLIN FRESENIUS te verskaf.

Jy kan enige vermoedelike ongunstige geneesmiddelreaksies aan jou gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aanmeld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om AMPICILLIN FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of benede 30 °C in 'n droë plek.

Neem alle ongebruikte medisyne terug na jou apteker.

Moet nie vries nie.

Beskerm teen lig.

Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat AMPICILLIN FRESENIUS bevat

Flessies steriele wit poeier bevattende 250 mg of 500 mg ampisillien as natriumampisillien.

Hoe AMPICILLIN FRESENIUS lyk en inhoud van die pakkie

AMPICILLIN FRESENIUS is 'n steriele oplosbare wit poeier in 'n verseëlde flessie.

Verpak in houers met 10 en 100.

Houer van die Registrasiesertifikaat

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

Erf 7, Growthpoint Business Park

Tonettistraat 162

Halfway House uitbreiding 7

Midrand

Gauteng

1685

Telefoonnommer: (011) 545 0000

Hierdie inligtingsblad was voorheen hersien op

16 Februarie 2026

Registrasienommer(s)

AMPICILLIN 250 mg FRESENIUS: H/20.1.2/25

AMPICILLIN 500 mg FRESENIUS: H/20.1.2/26

Toegang tot die ooreenstemmende Professionele Inligting

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