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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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.