

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 of getting 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 °C) and 24 hours under refrigeration (2 °C – 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 °C – 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 °C – 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

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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.