

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TAZOBAX 4 g/ 0,5 g Powder for solution for infusion

Piperacillin/ Tazobactam

Sugar free

Read all of this leaflet carefully before you are given TAZOBAX

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

What is in this leaflet

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

1. What TAZOBAX is and what it is used for

TAZOBAX contains piperacillin (a broad-spectrum penicillin antibiotic) and tazobactam (an inhibitor of many bacterial enzymes known as beta-lactamases). Piperacillin can kill many types of bacteria (germs).

Tazobactam can prevent some bacteria becoming resistant to the effects of piperacillin.

TAZOBAX may be used:

- in adults and adolescents for the treatment of bacterial infections in many different parts of the body such as those affecting the lower respiratory tract (lungs), urinary tract (kidneys and bladder), abdomen, skin or blood.;

- to treat bacterial infections in adults and children aged 2-12 years with low white cell counts (neutropenia), which affects resistance to infections.

In certain serious infections, your doctor may want you or your child to also receive another antibiotic together with TAZOBAX.

2. What you need to know before you are given TAZOBAX

TAZOBAX should not be administered to you:

- if you are hypersensitive (allergic) to piperacillin or tazobactam or any of the other ingredients of TAZOBAX (listed in section 6).
- If you had allergic reactions to antibiotics, known as penicillins, cephalosporins or beta-lactamase inhibitors. Ask your doctor or pharmacist if you are not certain.

Warnings and precautions

Tell your doctor or healthcare professional before given the injection:

- if you are prone to allergies, you may be more likely to have an allergic reaction to TAZOBAX;
- if you have diarrhoea (loose bowels). TAZOBAX may make it worse. You may get inflammation of your large intestines, which is a serious condition. If this happens, you need prompt medical attention. See **section 4**. Do not take any medicine for the diarrhoea before checking with your doctor;
- 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 have kidney or liver problems, 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 are taking or using medicines such as heparin or warfarin to prevent blood clots (see **section 2**);
- if you know that you have certain blood disorders such as prolonged clotting time and low white blood cell count. Your doctor may want to test your blood regularly, before and during treatment with TAZOBAX. Tell your doctor if you think you have developed a new or worsening infection.
- if you develop convulsions during the treatment. In this case, you should inform your doctor or other healthcare provider.

- If you are on a low sodium diet as TAZOBAX contains sodium
- if you think you developed a new or worsening infection. In this case, you should inform your doctor or other healthcare provider.

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.

Children

Piperacillin / tazobactam is not recommended for use in children below the age of 2 years due to insufficient data on safety and effectiveness.

Other medicines and TAZOBAX

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

(This includes complimentary or traditional medicines).

This is especially important with the following medicines, as they may influence the effect of TAZOBAX, or TAZOBAX may influence their effects:

- Medicines to relax your muscles during surgery. Tell your doctor if you are going to have a general anaesthetic.
- Medicines to thin your blood or to treat blood clots (e.g. heparin, warfarin or aspirin).
- Methotrexate (medicine used to treat cancer, arthritis or psoriasis). Piperacillin and tazobactam can increase the time it takes for methotrexate to leave your body.
- Medicines for gout (probenecid). This can increase the time it takes for piperacillin and tazobactam to leave your body.
- Aminoglycoside antibiotics - including gentamicin, tobramycin, streptomycin, neomycin, kanamycin. Tell your doctor about any kidney problems you may have.
- Medicines that reduce the level of potassium in your blood (such as “water pills” that increases your urinary output). See **section 2**.
- Oral contraceptives (birth control pills) because their effectiveness may be decreased by

piperacillin/tazobactam. Talk to your doctor about additional contraceptive methods.

Your doctor and pharmacist have more information on medicines to be careful with, or to avoid while you are given TAZOBAX.

If you need to have laboratory tests done, tell the doctor or laboratory staff you are receiving TAZOBAX. They may need to use special tests on your blood or urine to get the right results.

TAZOBAX with food, drink and alcohol

Not Applicable

Pregnancy, breastfeeding and fertility

No information is available on the safety and efficacy of TAZOBAX during pregnancy or 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 TAZOBAX.

Driving and using machines

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

TAZOBAX should not affect your ability to drive or handle machinery or tools. However, if you feel dizzy, do not drive or handle tools or machinery.

TAZOBAX contains sodium

TAZOBAX contains about 783,99 mg/vial of sodium. Tell your doctor if you are on a special diet to limit your salt intake.

3. How to receive TAZOBAX

You will not be expected to give TAZOBAX to yourself. It will be given to you by a person who is qualified to do so. Your doctor or nurse will give you TAZOBAX by slow injection (infusion) into a vein.

Your doctor will decide on the exact dose depending on the severity of your infection.

If you have kidney or liver problems, your doctor may need to adjust the dose of TAZOBAX or how often it is given. Your doctor may also want to test your blood to make sure that your treatment is working.

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

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

If you receive more TAZOBAX than you should

Since a healthcare professional will administer TAZOBAX, he/she will control the dosage. However, in the event of overdosage the doctor will manage the overdosage.

Please tell the doctor looking after you or your child, or the healthcare professional, if you notice signs of convulsions, diarrhoea or nausea, or if you think you or your child may have been given too much medicine.

If you forget to take TAZOBAX

Since a health care provider will administer TAZOBAX, it is unlikely that the dose will be missed. If you think that you have missed a dose of treatment, tell a doctor or nurse at once.

Do not receive a double dose to make up for forgotten individual doses.

If you stop receiving TAZOBAX

It is important that the course of treatment your doctor has prescribed is finished. Do not expect to stop receiving TAZOBAX just because you feel better. If you stop receiving treatment before the course is completed, the germs causing the disease may become resistant to TAZOBAX and your disease will get worse.

4. Possible side effects

TAZOBAX can have side effects. Not all side effects reported for TAZOBAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TAZOBAX, please consult your doctor, pharmacist or other healthcare provider for advice.

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

- 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 very fast heartbeat.
- Severe serious skin reactions with skin and mucous lining rashes and various skin eruptions (Stevens-Johnson syndrome). Some signs may be fever, hives (nettle rash), ulcers in the mouth, throat, nose, extremities and genitals with red and swollen eyes, blistering, peeling or loosening of the top layer of your skin (toxic epidermal necrolysis), which may be life-threatening.
- Severe, persistent bloody diarrhoea 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to TAZOBAX. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 will confirm this with a blood test.
- Changes in the number of red blood cells, white blood cells, platelets or protein in your blood (some signs may be: unexpected breathlessness, red or brown urine, nosebleeds, fatigue, and bruising).
- Unexpected excessive bleeding, particularly if you also take or receive blood thinning medicines such as warfarin.
- Abdominal pain, chest pain, shortness of breath as a result of a blockage to blood vessels of the lungs or intestines by a blood clot (embolism)
- Convulsions (fits or jerks) and headache.
- Heart rhythm disturbances (too quick, too slow or irregular heart beat), heart failure, heart attack.
- Eosinophilic pneumonia: A rare type of pneumonia where there is an increase in a type of white blood cell (eosinophils) in the lungs, causing inflammation.
- Yellowing of the eyes or skin (your liver may be affected), inflammation of the liver which can be

noticed by dark urine, feeling tired, fever.

- Allergic skin reaction, pale red, raised and itchy bumps on the skin (urticaria), small red bumps on the skin.
- Shivering, reactions at the site of the injection, including fever, reddening of the skin, pain, hardness or swelling.
- If you suffer from cystic fibrosis you may experience an increased incidence of fever and rashes.

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

- *Abnormal lab testing - Positive direct Coombs:* a test result indicating that your immune system is mistakenly attacking your red blood cells, which can cause anaemia.
- Iron deficiency (anaemia) – you may experience tiredness, dizziness, pale skin
- Increased blood clotting time which can increase the risk of bleeding.
- Sleeping problems (insomnia).
- Agitation (emotional disturbance), confusion, anxiety, hallucination (false perceptions), depression.
- Dizziness, trembling, dry mouth, feeling faint
- Eyes sensitive to light.
- Ringing in the ears.
- Runny nose, difficulty breathing, tight chest, coughing.
- Nausea (feeling sick), vomiting (being sick), diarrhoea (loose bowels), constipation, gas, blood in stool, heartburn/indigestion, stomach pain and bloating.
- Skin rashes, itchy skin.
- Sweating.
- Difficulty or pain on urination, inability to control urination, blood in the urine
- Increased levels of liver enzymes, creatinine or urea in the blood.
- Low levels of a protein called albumin in the blood, leading to a lower overall protein level in the blood.
- Increased levels of an enzyme called aspartate aminotransferase (AST) in the blood.
- Decreased levels of all proteins combined in the blood.

- Increased levels of an enzyme called alkaline phosphatase (ALP) in the blood.

Less frequent side effects:

- Feeling thirsty, changes in taste
- Low blood pressure, inflammation of the veins (phlebitis)
- Flushing of the upper body.
- Sore mouth, stomach pain and hiccups, blood in vomit
- Yeast infection causing itching or rash at the affected site.
- Low levels of potassium or glucose in the blood
- High levels of bilirubin (a yellow compound produced when red blood cells break down) in the blood.
- Joint and muscle pains in the legs and arms.

Unknown frequency

- Purple spots or patches on the skin which is caused by bleeding underneath the skin.
- Delirium – confused thinking and reduced awareness of your surroundings
- Kidney problems (swelling and problems with urination) – indicated by nausea, vomiting, muscle cramps, swelling of your ankles and feet

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.

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 (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TAZOBAX.

5. How to store TAZOBAX

- Store all medicines out of reach of children.

Dry powder:

Vials containing sterile TAZOBAX dry powder may be stored at controlled room temperature (at or below 25 °C).

Reconstituted solutions:

Your healthcare professional will store the solution according to the directions on the professional package insert.

- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TAZOBAX contains

- **The active substances** are piperacillin and tazobactam.

Each vial TAZOBAX contains sterile piperacillin sodium equivalent to 4 g piperacillin and sterile tazobactam sodium equivalent to 0,5 g tazobactam.

- **The other ingredient** ~~are~~ is sodium bicarbonate.

What TAZOBAX looks like and contents of the pack

Glass vials containing a white to off-white powder.

Reconstituted solution: Clear, colourless to pale yellow liquid, free from foreign matter.

Type I clear borosilicate 50 ml glass vials, sealed by type 1 butyl rubber stoppers and aluminium plastic cap. Finally the product is packed in a carton with a package insert.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106, 16th Road

Midrand

1686

087 742 1860

This leaflet was revised in

22 May 2025

Registration number

37/20.1.1/0454