

Applicant: Oethmaan Biosims (Pty) Ltd	SAHPRA approval date: 6 March 2025
Product: TAZLIN 4,5	Dosage form and strength: Each vial contains piperacillin sodium equivalent to 4 g piperacillin & tazobactam sodium equivalent to 500 mg tazobactam powder for solution for injection

PATIENT INFORMATION LEAFLET - APPROVED

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SCHEDULING STATUS:

S4

TAZLIN 4,5, Powder for solution for injection

4 g Piperacillin and 500 mg Tazobactam

Contains 9,39 mmol (or 216 mg) sodium per vial

Sugar free

Read all of this leaflet carefully before you start taking TAZLIN 4,5

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or other health care provider.
- TAZLIN 4,5 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TAZLIN 4,5 is and what it is used for
2. What you need to know before you take TAZLIN 4,5
3. How to take TAZLIN 4,5

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4. Possible side effects
5. How to store TAZLIN 4,5
6. Contents of the pack and other information

1. What TAZLIN 4,5 is and what it is used for

TAZLIN 4,5 contains a penicillin antibiotic and a beta-lactamase inhibitor, which are used to treat infections caused by bacteria. The beta-lactamase inhibitor is added to the penicillin to protect the penicillin from certain substances (enzymes) that will destroy the penicillin antibiotic before it can kill the bacteria.

TAZLIN 4,5 is indicated for the treatment of the following bacterial infections:

Adults:

Community acquired pneumonia.

Intra-abdominal infections

Skin and soft tissue infections

Gynaecological infections

Children:

TAZLIN 4,5 plus an aminoglycoside is indicated for bacterial infections in neutropenic patients.

In hospitalised children aged 2 to 12 years, TAZLIN 4,5 is indicated for the treatment of serious intra-abdominal infections. It has not been evaluated in this indication for paediatric patients below the age of 2 years.

Your doctor has prescribed this medicine for your specific condition.

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2. What you need to know before you are given TAZLIN 4,5

TAZLIN 4,5 should not be given to you if you:

- Have a known hypersensitivity (allergy) to penicillins, cephalosporin antibiotics or to medicines called beta-lactamase inhibitors.

Warnings and precautions

Take special care with TAZLIN 4,5:

Before you are given TAZLIN 4,5 Powder for solution for injection/infusion

Please tell your doctor if:

- You have ever had any unusual or allergic reaction to any of the penicillins, cephalosporins, or beta-lactamase inhibitors or suffer from any other allergies.
- You have any kidney problems or receiving haemodialysis.
- You have a history of bleeding problems. Tell your doctor immediately if you notice that you are bleeding or bruising more easily than normal.
- You have cystic fibrosis.

During treatment:

- TAZLIN 4,5 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).
- Tell your doctor immediately if you have diarrhoea with severe stomach pain with cramps, fever and severe watery stools which may become bloody. Your doctor will stop treatment with TAZLIN 4,5 and start treatment for the diarrhoea.

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- 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.
- Haemophagocytic lymphohistiocytosis

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.
- Tell your doctor if you develop symptoms of a new infection.
- With high doses of TAZLIN 4,5 you may get nervous system complications such as convulsions (fits).
- Tell your doctor if you have low levels of potassium in your blood or if you are taking diuretics (for heart problems or high blood pressure) or medicines for cancer. Your doctor might take a blood sample from time to time to test the levels of potassium in your blood.
- Severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart problem called Kounis syndrome (also known as allergic angina), which can cause chest pain, shortness of breath, or a fast or irregular heartbeat.
- Any unusual blistering or skin eruptions. TAZLIN 4,5 can cause a serious skin condition called Linear IgA bullous dermatosis (LABD).

Other medicines and TAZLIN 4,5

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Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines may interact with your **TAZLIN 4,5 Powder for solution for injection/infusion** when you take them together and may either cause additional side effects or may not work as well:

- Anticoagulants (blood-thinners such as warfarin and heparin).
- Other antibiotics such as tetracycline, chloramphenicol, vancomycin, tobramycin.
- Methotrexate (used in cancer treatment).
- Muscle relaxing medicines (eg. Vecuronium).
- Probenecid (used for gout).
- Oral contraceptives, as the effectiveness of the oral contraceptive medicine may be reduced.

Not all medicine interactions are described in this leaflet. It is therefore very important that you tell your doctor or healthcare professional of all the other medicines you are currently taking.

TAZLIN 4,5 may interfere with certain laboratory tests (including certain urine glucose tests), possibly causing false test results. Make sure lab personnel and all your doctors know you use TAZLIN 4,5.

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 professional for advice before receiving TAZLIN 4,5.

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Do not receive TAZLIN 4,5 if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent TAZLIN 4,5 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 TAZLIN 4,5 affects them.

TAZLIN 4,5 is not known to affect ability to drive or operate machines.

TAZLIN 4,5 contains sodium

Talk to your doctor or pharmacist if you need 3 or more vials daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to receive TAZLIN 4,5

TAZLIN 4,5 is for intravenous use only.

You will not be expected to give yourself TAZLIN 4,5. 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.

The usual dosage for adults and children over 12 years is 4,5 g TAZLIN 4,5 (4 g piperacillin/500 mg tazobactam) given every 8 hours.

Children aged 12 years and under with low white blood cell counts: The usual dose for children weighing over 50 kg is the same as that for adults, including an aminoglycoside antibiotic. For

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children weighing less than 50 kg, your doctor will calculate the dose depending on your child's weight.

Children aged 2 to 12 years of age hospitalized with intra-abdominal infection:

Weighing less than 40 kg: The usual dose is 112,5 mg/kg TAZLIN 4,5 every eight hours. Your doctor will calculate the dose depending on your child's weight.

Weighing more than 40 kg: The usual dose is the same as that for adults i.e. 4,5 g TAZLIN 4,5 every eight hours.

The length of time you will be given TAZLIN 4,5 depends on the type and severity of your infection. You will be given TAZLIN 4,5 for 5 to 14 days and for 48 hours after all signs of illness and fever have gone.

If you have kidney problems, your doctor may need to adjust the dose of TAZLIN 4,5 or how often it is given.

If you receive more TAZLIN 4,5 than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

Since a healthcare provider will administer TAZLIN 4,5, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If a dose of TAZLIN 4,5 is missed

Since a healthcare provider will administer TAZLIN 4,5, it is unlikely that the dose will be missed.

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4. Possible side effects:

TAZLIN 4,5 can have side effects.

Not all side effects reported for TAZLIN 4,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TAZLIN 4,5 please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving TAZLIN 4,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching all over the body.

These are all very serious side effects. If you have them, you may have had a serious reaction to TAZLIN 4,5. 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: The following side effects occur less frequently:

- Pseudomembranous colitis (infection of the colon resulting in watery and sometimes bloody stools).
- A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis).
- Inflammation of the liver, resulting in abdominal pain, dark urine, pale stools, weakness, fatigue.

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- Less urine than is normal for you.

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

- Headache
- Diarrhoea (mild), nausea, vomiting stomach pain

Less frequent side effects

- Yeast infection (thrush)
- Chest pain
- Low blood pressure, inflammation of a vein with or without formation of a blood clot
- Increases in levels of liver enzymes in the blood, increased levels of bilirubin in the blood
- Rash, itchy skin, hives
- Joint pain, muscle pain
- Shivering, chills and fever in cystic fibrosis patients, reactions at the site of the injection

Frequency unknown

- Changes in the number of red or white blood cells, platelets or other components in your blood.
- Bleeding problems (nose bleeds, red or purple discoloured spots on the skin due to bleeding from small blood vessels, increased bleeding time).
- Severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart

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problem called Kounis syndrome, which can cause chest pain, shortness of breath, or a fast or irregular heartbeat. If you experience any of these symptoms, stop taking TAZLIN 4,5 and seek medical attention immediately.

- Reduced levels of albumin, protein, potassium or glucose in your blood.
- Sleeping problems (insomnia).
- Convulsions (fits).
- Flushing.
- Constipation, stomach pain and heartburn/indigestion, mouth sores.
- Yellowing of the eyes or skin (jaundice).
- Severe skin reactions, including Linear IgA bullous dermatosis (LABD). Symptoms can include itchy or painful blisters, often in a line or cluster, and areas of raw or denuded skin. If you experience any of these symptoms, stop taking TAZLIN 4,5 and seek medical attention immediately.
- Large fluid filled blisters on the skin (bullous dermatitis), rash resembling a bull's-eye (erythema multiforme).
- Increased levels of creatinine or urea in the blood, kidney problems (swelling and problems with urination), inflammation of the kidneys, kidney failure.
- Laboratory test: A positive antiglobulin test (when the blood is checked to see if it contains certain antibodies).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store TAZLIN 4,5

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Dry powder: Store below 25 °C.

Reconstituted solution: Store for 24 hours at 2 to 8 °C.

Any unused solution must be discarded.

Do not use TAZLIN 4,5 after the expiry date stated on the container.

Return all unused medicine to your pharmacist for safe disposal.

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

6. Contents of the pack and other information

What TAZLIN 4,5 contains

The active substances are:

Each TAZLIN 4,5 100 ml glass bottle contains piperacillin sodium equivalent to piperacillin 4 g and tazobactam sodium equivalent to tazobactam 500 mg.

TAZLIN 4,5 does not contain any other ingredients.

What TAZLIN 4,5 looks like and contents of the pack

TAZLIN 4,5 Powder for solution for injection/infusion is a white to yellowish powder.

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Ready-for-use solution: Clear colourless to yellowish solution free from fibres and particulate matter.

TAZLIN 4,5 Powder for solution for injection/infusion is available in 100 ml clear glass bottles with grey bromobutyl rubber stoppers and plastic flip-off caps.

Name, Business Address and Telephone Number of the Holder of the Certificate of Registration

Oethmaan Biosims (Pty) Ltd
207A Sherwood House
Greenacres Office Park
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Victory Park
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2195
Telephone number: 011 433 0602

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Access to the corresponding Professional Information

www.oethmaan.co.za

Telephone number: 011 433 0602

Email: info@oethmaan.co.za

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