

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Piperacillin/Tazobactam Sandoz® 2.25 g vials

Piperacillin/Tazobactam Sandoz® 4.5 g vials

powder for solution for injection or infusion



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1. WHAT PIPERACILLIN/TAZOBACTAM SANDOZ IS AND WHAT IT IS USED FOR

Piperacillin belongs to the group of medicines called broad spectrum penicillin antibiotics, which can kill many types of bacteria. Tazobactam prevents some bacteria from resisting the effects of piperacillin. This means that when piperacillin and tazobactam are given together, more types of bacteria are killed.

Piperacillin/Tazobactam Sandoz is used in adults to treat bacterial infections affecting your chest, urinary tract (kidneys and bladder), abdomen or skin.

Piperacillin/Tazobactam Sandoz is used in children aged 2-12 to treat bacterial infections in children with low white cell counts (reduced resistance to infections).

2. BEFORE YOU USE PIPERACILLIN/TAZOBACTAM

Do not use Piperacillin/Tazobactam Sandoz

- if you are allergic (hypersensitive) to piperacillin, other antibiotics called penicillins or cephalosporins, tazobactam, or other medicines called beta-lactamase inhibitors.

Take special care with Piperacillin/Tazobactam Sandoz

- if you have allergies. If you have several allergies make sure you tell your doctor or nurse before receiving this product.
- if you are pregnant, think you may be pregnant, or are breastfeeding.
- if you have low levels of potassium in your blood. Your doctor may want to perform regular blood tests during treatment.
- if you have kidney or liver problems, or are receiving haemodialysis. Your doctor may want to check your kidneys before you take this medicine, and may perform regular blood tests during treatment.
- if you are on a low sodium diet.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines may interact with piperacillin and tazobactam. These include:

- Probenecid (for gout). This can increase the time it takes for piperacillin and tazobactam to leave your body.
- Medicines to thin your blood or to treat blood clots (e.g. heparin, warfarin or aspirin).
- Medicines used to relax our muscles during surgery. Tell our doctor if you

If you have any further questions on the use of this product, ask your doctor or healthcare professional.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Piperacillin/Tazobactam Sandoz can cause side effects, although not everybody gets them.

If any of the following happens, stop taking piperacillin/tazobactam and tell your doctor or nurse immediately:

- Rare side effects (that affect less than 1 person in 1,000):
Severe allergic reaction (sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat), bloody diarrhoea.
- Very rare side effects (that affect less than 1 person in 10,000):
Peeling and blistering of the skin, mouth, eye and genitals.

Other possible side effects:

Common side effects (affecting less than 1 in 10 patients but more than 1 in 100) are:

- diarrhoea
- nausea and vomiting
- skin rashes

Uncommon side effects (affecting less than 1 in 100 patients but more than 1 in 1000) are:

- thrush
- mild allergic reactions
- headache
- difficulty sleeping
- low blood pressure (felt as light-headedness)
- inflammation of the veins (felt as tenderness or redness in the affected area)
- constipation
- upset stomach
- jaundice (yellowing of the skin or whites of the eyes)
- mouth ulcers
- itching
- fever or hot flushes
- swelling or redness around the injection site
- changes in results of blood tests of kidney and liver function
- changes in the number of cells in the blood (red cells, white cells and platelets)

Rare side effects (affecting less than 1 in 1,000 patients but more than 1 in 10,000) are:

- unusual bruising and bleeding
- weakness
- hallucinations (seeing or hearing things)
- convulsions or twitching
- dry mouth

are going to have a general anaesthetic.

- Methotrexate (for cancer, arthritis or psoriasis). Piperacillin and tazobactam can increase the time it takes for methotrexate to leave your body.
- Medicines that reduce the level of potassium in your blood (e.g. water tablets, or some medicines for cancer).

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are trying for a baby, tell your doctor or nurse before receiving this product.

Piperacillin and Tazobactam can pass to a baby in the womb or through breast milk. If you are pregnant or breast-feeding, your doctor will decide whether Piperacillin/Tazobactam Sandoz is right for you.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

However, side effects could occur which may influence your ability to drive or use machines (see section 4).

Important information about some of the ingredients of this product

This medicinal product contains 9.40 mmol (equivalent to 216 mg) or 4.72 mmol (109 mg) of sodium per vial of powder for solution for injection or infusion.

To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE PIPERACILLIN/TAZOBACTAM SANDOZ

Your doctor or nurse will give you this medicine by slow injection (for 3-5 minutes) or through a drip (for 20-30 minutes) into one of your veins. The dose of medicine given to you depends on what you are being treated for, your age, and whether or not you have kidney problems.

Adults and children aged 2-12

The usual dose is 4g/0.5g piperacillin/tazobactam given every 8 hours. Your doctor may reduce the dose depending on how serious your infection is.

If you are unable to fight infections normally, the usual dose is 4g/0.5g piperacillin/tazobactam given every 6 hours at the same time as another antibiotic called an aminoglycoside, which is given into one of your veins. The two medicines should be given in separate syringes or drips.

In children, the doctor will calculate the dose depending on your child's weight. You will be given Piperacillin/Tazobactam Sandoz until the signs of infection have gone, and then, normally, for another 48 hours to make sure the infection has gone completely.

Children under 2 years of age

Piperacillin/Tazobactam is not recommended for use in children below 2 years old due to insufficient data on safety.

If you have kidney problems

Your doctor may need to reduce the dose of Piperacillin/Tazobactam Sandoz or how often you are given it. Your doctor may also want to test your blood to make sure that your treatment is at the right dose, especially if you have to take this medicine for a long time.

If you are given more Piperacillin/Tazobactam Sandoz than you should

As you will be given Piperacillin/Tazobactam Sandoz by a doctor or nurse, you are unlikely to be given the wrong dose. However, if you experience bad side effects or think you have been given too much, tell your doctor immediately.

If you miss a dose Piperacillin/Tazobactam Sandoz

If you think you have not been given a dose of Piperacillin/Tazobactam Sandoz, tell your doctor immediately.

- abdominal pain
- increased sweating
- eczema and other skin problems
- joint and muscle pain
- kidney problems
- tiredness
- water retention (seen as swollen hands, ankles or feet).

Very rare side effects (in less than 1 in 10,000 patients) are:

- low blood glucose levels which may make you confused and shaky
- reduced blood concentration of potassium which can cause muscle weakness, twitching or abnormal heart rhythm

Your doctor may want to perform tests during your treatment to measure any changes. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. HOW TO STORE PIPERACILLIN/TAZOBACTAM SANDOZ

Keep out of the reach and sight of children.

Do not use Piperacillin/Tazobactam Sandoz after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Storage of powder for solution for injection or infusion:

Do not store above 25°C.

Storage of reconstituted solution:

24 hours at room temperature (20°C – 25°C) or 48 hours refrigerated (2°C – 8°C)

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Piperacillin/Tazobactam Sandoz contains

• Active substances:

The active substances are piperacillin (as sodium salt) and tazobactam (as sodium salt).

Piperacillin/Tazobactam Sandoz 2.25 g contains 2 g piperacillin and 250 mg tazobactam.

Piperacillin/Tazobactam Sandoz 4.5 g contains 4 g piperacillin and 500 mg tazobactam.

• Other ingredients:

The medicinal product contains no other ingredients than the active substances.

What Piperacillin/Tazobactam Sandoz looks like and contents of the pack

Piperacillin/Tazobactam Sandoz 2.25 g is a white to yellowish powder for solution for injection or infusion packaged in glass vials. The vials are packed in carton boxes. Each box contains 1, 5, 10, 12 or 50 glass vials. Not all pack sizes may be marketed.

Piperacillin/Tazobactam Sandoz 4.5 g is a white to yellowish powder for solution for injection or infusion packaged in glass bottles. The bottles are packed in carton boxes. Each box contains 1, 5, 10, 12 or 50 glass bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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