

PACKAGE LEAFLET: INFORMATION FOR THE USER

Piperacillin/Tazobactam Teva 2 g/250 mg powder for solution for infusion **Piperacillin/Tazobactam Teva 4 g/500 mg powder for solution for infusion**

piperacillin/ tazobactam

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.

In this leaflet:

1. What Piperacillin/Tazobactam Teva is and what it is used for
2. Before you use Piperacillin/Tazobactam Teva
3. How to use Piperacillin/Tazobactam Teva
4. Possible side effects
5. How to store Piperacillin/Tazobactam Teva
6. Further information

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

Piperacillin belongs to the group of medicines known as “broad-spectrum penicillin antibiotics”. It can kill many kinds of bacteria. Tazobactam can prevent some resistant bacteria from surviving the effects of piperacillin. This means that when piperacillin and tazobactam are given together, more types of bacteria are killed.

Piperacillin/Tazobactam Teva is used in adults and adolescents to treat bacterial infections, such as those affecting the lower respiratory tract (lungs), urinary tract (kidneys and bladder), abdomen, skin or blood. Piperacillin/Tazobactam Teva may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Piperacillin/Tazobactam Teva is used in children aged 2-12 to treat infections of the abdomen such as appendicitis, peritonitis (infection of the fluid and lining of the abdominal organs), and gallbladder (biliary) infections. Piperacillin/Tazobactam Teva may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

In certain serious infections, your doctor may consider using Piperacillin/Tazobactam Teva in combination with other antibiotics.

2. BEFORE YOU USE PIPERACILLIN/TAZOBACTAM TEVA

Do NOT use Piperacillin/Tazobactam Teva:

- if you are allergic (hypersensitive) to piperacillin or tazobactam.
- if you are allergic (hypersensitive) to antibiotics known as penicillins, cephalosporins or other beta-lactamase inhibitors, as you may be allergic to Piperacillin/Tazobactam Teva.

Take special care with Piperacillin/Tazobactam Teva

- if you have allergies. If you have several allergies, make sure you tell your doctor or other healthcare professional before receiving this product.

- if you are suffering from diarrhoea before, or if you develop diarrhoea during or after your treatment. In this case, make sure you tell your doctor or other healthcare professional immediately. Do not take any medicine for the diarrhoea without first checking with your doctor.
- if you have low levels of potassium in your blood. Your doctor may want to check your kidneys before you take this medicine and may 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 taking certain medicines (called anticoagulants) to avoid an excess of blood clotting (see also **Using other medicines** in this leaflet) or any unexpected bleeding occurs during the treatment. In this case, you should inform your doctor or other healthcare professional immediately.
- if you develop convulsions during the treatment. In this case, you should inform your doctor or other healthcare professional.
- if you think you developed a new or worsening infection. In this case, you should inform your doctor or other healthcare professional.
- if you are on a low sodium diet.

Children below 2 years

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

Using other medicines

Please tell your doctor or other healthcare professional 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:

- medicine for gout (probenecid). 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 your muscles during surgery. Tell your doctor if you are going to have a general anaesthetic.
- 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 that reduce the level of potassium in your blood (e.g. tablets enhancing urination or some medicines for cancer).
- medicines containing the other antibiotics tobramycin or gentamycin. Tell your doctor if you have kidney problems.

Effect on laboratory tests

Tell the doctor or laboratory staff that you are taking Piperacillin/ Tazobactam Teva if you have to provide a blood or urine sample.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are trying to become pregnant, tell your doctor or other healthcare professional before receiving this product. Your doctor will decide if Piperacillin/ Tazobactam Teva is right for you.

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

Driving and using machines

The use of Piperacillin/Tazobactam Teva is not expected to affect the ability to drive or use machines.

Important information about some of the ingredients of Piperacillin/Tazobactam Teva

Piperacillin/Tazobactam Teva 2 g/ 250 mg contains 4.7 mmol (108 mg) of sodium.

Piperacillin/Tazobactam Teva 4 g/500 mg contains 9.4 mmol (216 mg) of sodium.

This should be taken into consideration if you are on a controlled-sodium diet.

3. HOW TO USE PIPERACILLIN/TAZOBACTAM TEVA

Your doctor or other healthcare professional will give this medicine through an infusion (a drip for 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 adolescents aged 12 years or older

The usual dose is 4 g piperacillin/500 mg tazobactam given every 6-8 hours, which is given into one of your veins (directly into the blood stream).

Children aged 2 to 12 years

The usual dose for children with abdominal infections is 100 mg / 12.5 mg / kg of body weight of piperacillin / tazobactam given every 8 hours into one of your veins (directly into the blood stream). The usual dose for children with low white blood cell counts is 80 mg / 10 mg / kg of body weight of piperacillin / tazobactam given every 6 hours into one of your veins (directly into the blood stream).

Your doctor will calculate the dose depending on your child's weight but the daily dose will not exceed 4 g / 500 mg of Piperacillin/Tazobactam Teva.

You will be given Piperacillin/Tazobactam Teva until the sign of infection has gone completely (5 to 14 days).

Patients with kidney problems

Your doctor may need to reduce the dose of Piperacillin/Tazobactam Teva 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 Teva than you should

As you will be given Piperacillin/Tazobactam Teva by a doctor or other healthcare professional, you are unlikely to be given the wrong dose. However, if you experience side effects, such as convulsions, or think you have been given too much, tell your doctor immediately.

If you miss a dose of Piperacillin/Tazobactam Teva

If you think you have not been given a dose of Piperacillin/Tazobactam Teva, tell your doctor or other healthcare professional immediately.

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

4. POSSIBLE SIDE EFFECTS

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

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 other healthcare professional.

The serious side effects of Piperacillin/Tazobactam Teva are:

- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or trouble breathing
- severe rash, itching or hives on the skin
- yellowing of the eyes or skin
- damage to blood cells (the signs include: being breathless when you do not expect it, red or brown urine, nosebleeds and bruising)

If you notice any of the above, see a doctor straight away. For frequency of these reactions, refer to the information below.

Possible side effects are listed according to the following categories:

- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000

Common side effects:

- diarrhoea, vomiting, nausea
- skin rashes

Uncommon side effects:

- thrush
- (abnormal) decrease in white blood cells (leukopenia, neutropenia) and platelets (thrombocytopenia)
- allergic reaction
- headache, sleeplessness
- low blood pressure, inflammation of the veins (felt as tenderness or redness in the affected area)
- jaundice (yellow staining of the skin or whites of the eyes), inflammation of the mucous lining of the mouth, constipation, indigestion, stomach upset
- increase of certain enzymes in the blood (alanine aminotransferase increased, aspartate aminotransferase increased)
- itching, nettle rash
- increase of muscle metabolism product in the blood (blood creatinine increased)
- fever, injection site reaction
- yeast infection (candidal superinfection)

Rare side effects:

- (abnormal) decrease of red blood cells or blood pigment / haemoglobin, (abnormal) decrease of red blood cells due to premature breakdown (degradation) (haemolytic anaemia), small spot bruising (purpura), bleeding of the nose (epistaxis) and bleeding time prolonged, (abnormal) increase of a specific type of white blood cells (eosinophilia)
- severe allergic reaction (anaphylactic/anaphylactoid reaction, including shock)
- flushed red skin
- a certain form of infection of the colon (pseudomembranous colitis), abdominal pain
- inflammation of the liver (hepatitis), increase of a blood pigments breakdown product (bilirubin), increase of certain enzymes in the blood (blood alkaline phosphatase increased, gamma-glutamyltransferase increased)
- skin reactions with redness and formation of skin lesions (exanthema, erythema multiforme), skin reactions with blistering (bullous dermatitis)
- joint and muscle pain
- poor kidney functions and kidney problems
- rigors chill / rigidity

Very rare side effects:

- severe decrease of granular white blood cells (agranulocytosis), severe decrease of red blood cells, white blood cells and platelets (pancytopenia)
- prolonged time for blood clot formation (prolonged partial thromboplastin time, prothrombin time prolonged), abnormal lab test (positive direct Coombs), increase of platelets (thrombocythaemia)
- decrease of potassium in the blood (hypokalaemia), decrease of blood sugar (glucose), decrease of the blood protein albumin, decrease of blood total protein
- detachment of the top layer of the skin all over the body (toxic epidermal necrolysis), serious bodywide allergic reaction with skin and mucous lining rashes and various skin eruptions (Stevens-Johnson Syndrome)
- blood urea nitrogen increased

Piperacillin therapy has been associated with an increased incidence of fever and rash in cystic fibrosis patients.

5. HOW TO STORE PIPERACILLIN/TAZOBACTAM TEVA

Keep out of the reach and sight of children.

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

Unopened vials:

This medicinal product does not require any special storage conditions.

Reconstituted solution

Chemical and physical in use stability has been demonstrated for 8 hours when stored below 25°C or for 48 hours when stored in a refrigerator (2-8°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 when stored in a refrigerator (2-8°C), unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

For single use only. Discard any unused solution.

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 to protect the environment.

6. FURTHER INFORMATION

What Piperacillin/Tazobactam Teva contains

- The active substances are piperacillin and tazobactam.
Each vial contains 2 g piperacillin (as sodium salt) and 250 mg tazobactam (as sodium salt).
Each vial contains 4 g piperacillin (as sodium salt) and 500 mg tazobactam (as sodium salt).

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

Piperacillin/Tazobactam Teva 2 g/250 mg is a white to off-white powder supplied in a vial.
Pack sizes: 1 vial, 10 vials.

Piperacillin/Tazobactam Teva 4 g/500 mg is a white to off-white powder supplied in a vial.
Pack sizes: 1 vial, 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
<[To be completed nationally]>

Manufacturer
<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:
<[To be completed nationally]>

This leaflet was last approved in {MM/YYYY}.

The following information is intended for medical or healthcare professionals only:

Incompatibilities

Lactated Ringer's solution is not compatible with Piperacillin/Tazobactam Teva.

Whenever Piperacillin/Tazobactam Teva is used concurrently with another antibiotic (e.g. aminoglycosides), the substances must be administered separately. The mixing of beta-lactam antibiotics with aminoglycoside, *in vitro*, can result in substantial inactivation of the aminoglycoside.

Piperacillin/Tazobactam Teva should not be mixed with other substances in a syringe or infusion bottle since compatibility has not been established.

Because of chemical instability, piperacillin/tazobactam should not be used with solutions containing only sodium bicarbonate.

Piperacillin/Tazobactam Teva should not be added to blood products or albumin hydrolysates.

Reconstitution Directions

Preparation of a reconstituted solution

Compatible Diluents for reconstitution:

- Sterile water for injection
- Sodium Chloride 9 mg/ml (0.9%) for injection

1 vial of Piperacillin/Tazobactam Teva 2 g/250 mg should be reconstituted with 10 ml of one of the solvents listed above.

1 vial of Piperacillin/Tazobactam Teva 4 g/500 mg should be reconstituted with 20 ml of one of the solvents listed above.

Preparation of an intravenous infusion

The reconstituted solution should be further diluted to the desired volume (e.g. 50 to 150 ml) with one of the compatible diluents for intravenous use listed below:

- Sterile water for injection (with a maximum recommended volume per dose of 50 ml)
- Sodium Chloride 9 mg/ml (0.9%) solution for infusion
- Glucose 50 mg/ml (5%) in water for injection
- Glucose 50 mg/ml (5%) in sodium chloride 9 mg/ml (0.9%) solution
- Dextrane 60 mg/ml (6%) in sodium chloride 9 mg/ml (0.9%) solution.

For single use only. Discard any unused solution.

The reconstitution/dilution is to be made under aseptic conditions.

To ensure full reconstitution of the contents, once the solvent has been added, the vial should be inverted and shaken until the powder has completely dissolved.

The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if it is clear and free from particles.