

PACKAGE LEAFLET: INFORMATION FOR THE USER

**PIPERACILLIN/TAZOBACTAM  
FOR INJECTION USP  
2.25G / 4.5G  
TAJ PHARMA**

**Piperacillin and tazobactam**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

**WHAT IS IN THIS LEAFLET:**

1. What Piperacillin / Tazobactam is and what it is used for
2. What you need to know before you use Piperacillin / Tazobactam
3. How to use Piperacillin / Tazobactam
4. Possible Side Effects
5. How to store Piperacillin / Tazobactam
6. Contents of the pack and other information

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

Piperacillin belongs to the group of medicines known as “broad spectrum penicillin antibiotics”. It can kill many types 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 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 may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Piperacillin / Tazobactam is used in children aged 2-12 years 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 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 in combination with other antibiotics.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE PIPERACILLIN/TAZOBACTAM**

**Do not use Piperacillin / Tazobactam**

- if you are allergic (hypersensitive) to

piperacillin or tazobactam

- if you are allergic (hypersensitive) to antibiotics known as penicillins, cephalosporins, or other betalactamase inhibitors, as you may be allergic to Piperacillin / Tazobactam

**Warning and precautions:**

Talk to your doctor or other healthcare professional before using Piperacillin / Tazobactam:

- 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 think you developed a new or worsening infection. In this case, you should inform your doctor or other healthcare professional
- 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 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 develop convulsions during the treatment. In this case, you should inform

your doctor or other healthcare professional

- 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.

### 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.

### Other medicines and Piperacillin / Tazobactam

Tell your doctor or other healthcare professional if you are taking or have recently taken or might take 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 your doctor or laboratory staff that you are taking Piperacillin/Tazobactam if you had to provide a blood or urine sample.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or other healthcare professional for advice before taking this medicine.

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 is right for you

### Driving and using machines

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

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

Piperacillin / Tazobactam 2g/0.25g contains 4.70 mmol (108 mg) of sodium. Piperacillin / Tazobactam 4g/0.5g contains 9.39 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

Take this medicine exactly as your doctor or healthcare professional has told you. Check with your doctor or healthcare professional if you are not sure. Your doctor or other healthcare professional will give you 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.

### Use in adults and adolescents aged 12 years or older)

The usual dose is 4g/0.5g Piperacillin / Tazobactam given every 6-8 hours, which is given into one of your veins (directly into the blood stream).

**Use in 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 / 0.5 g of Piperacillin/Tazobactam.

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

**Use in patients with kidney problems** Your doctor may need to reduce the dose of

Piperacillin / Tazobactam 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 take more Piperacillin/ Tazobactam than you should** As you will receive Piperacillin/ Tazobactam from 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 forgot to take Piperacillin/ Tazobactam** If you think you have not been given a dose of Piperacillin / Tazobactam, tell your doctor or other healthcare professional immediately. If you have any further questions on the use of this medicine, ask your doctor or other healthcare professional.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. See a doctor immediately if you experience any of these potentially serious side effects:

- Serious skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs include ulcers in the mouth, throat, nose, extremities, genitals and conjunctivitis (red and swollen eyes). The rash may progress to widespread blistering or peeling of the skin

- and potentially may be life threatening
- 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)
- severe or persistent diarrhoea accompanied by a fever or weakness
- unexpected bleeding, particularly if you are taking anticoagulants such as warfarin

#### **Other possible side effects:**

**Common side effects** (may affect up to 1 in 10 people)

- diarrhoea, vomiting, nausea
- skin rashes

**Uncommon side effects** (may affect up to 1 in 100 people)

- 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** (may affect up to 1 in 1,000 people) (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** (may affect up to 1 in 10,000 people)

- 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

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### **5. HOW TO STORE PIPERACILLIN/TAZOBACTAM**

##### **Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the carton and vial after "Exp". The expiry date refers to the last day of that month. Unopened vials: Do not store above 25°C. Store in the original package. The reconstituted/diluted solution should be used within 5 hours when stored at 20-25°C and within 24 hours when stored at 2 - 8°C. Only clear solutions, free of visible particles should be used.

For single use only.

Discard any unused solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines

you no longer use. These measures will help to protect the environment.

#### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

##### **What Piperacillin / Tazobactam contains**

The active substances are Piperacillin and Tazobactam.

Each vial contains 2 g piperacillin (as sodium salt) and 0.25 g tazobactam (as sodium salt). Each vial contains 4 g piperacillin (as sodium salt) and 0.5 g tazobactam (as sodium salt)

##### **What Piperacillin / Tazobactam looks like and contents of the pack**

White to off-white powder. Clear glass vial with a rubber stopper sealed with an aluminium flip-off seal.

Pack sizes: 1 x 1 vial containing powder for solution for infusion. 10 x 1 vial containing powder for solution for infusion.

Not all pack sizes may be marketed.

#### **7. MANUFACTURED IN INDIA BY:**

##### **TAJ PHARMACEUTICALS LTD.**

Mumbai, India

Unit No. 214. Old Bake House,  
Maharashtra chambers of Commerce Lane,  
Fort, Mumbai - 400001  
at: Gujarat, INDIA.

Customer Service and Product Inquiries:  
1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m. EST

E-mail: [tajgroup@tajpharma.com](mailto:tajgroup@tajpharma.com)