

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion

**Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion is and what it is used for
2. What you need to know before you use Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion.
3. How to use Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion
4. Possible side effects
5. How to store Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion
6. Contents of the pack and other information

#### **1. What Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion 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 4 g/0.5 g powder for solution for infusion 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 4 g/0.5 g powder for solution for infusion may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion 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 4 g/0.5 g powder for solution for infusion 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 4 g/0.5 g powder for solution for infusion in combination with other antibiotics.

#### **2. What you need to know before you use Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion**

##### **Do not use Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion**

- if you are allergic to piperacillin or tazobactam or any of the other ingredients of this medicine (listed in section 6).

- if you are allergic to antibiotics known as penicillins, cephalosporins or other beta-lactamase inhibitors, as you may be allergic to Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion.

### **Warnings and precautions**

#### **Talk to your doctor before using Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion**

- 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 **Other medicines and Piperacillin/Tazobactam** 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.

### **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 any other medicines, including medicines obtained without a prescription. Some medicines may interact with piperacillin and tazobactam.

These include:

- medicines 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 gentamicin. Tell your doctor if you have kidney problems.
- Combined use of piperacillin/tazobactam and vancomycin may be associated with an increased risk of acute kidney damage.

#### *Effect on laboratory tests*

Tell the doctor or laboratory staff that you are taking Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion if you have 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 receiving this medicine.

Your doctor will decide if Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion 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 4 g/0.5 g powder for solution for infusion is right for you.

#### *Driving and using machines*

The use of Piperacillin/Tazobactam 4g/0.5 g powder for solution for infusion is not expected to affect the ability to drive or use machines.

#### *Important information about some of the ingredients of Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion*

Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion contains 9.44 mmol (217 mg) of sodium.

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

### **3. How to use Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion**

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 recommended dose is 4 g/0.5 g 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 recommended 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 4 g/0.5 g powder for solution for infusion.

You will be given Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion 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 4 g/0.5 g powder for solution for infusion 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 receive more Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion than you should*

As you will receive Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion 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 miss a dose of Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion*

If you think you have not been given a dose of Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion, 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** of Piperacillin/Tazobactam:

The serious side effects (with frequency in brackets) of Piperacillin/Tazobactam are:

- serious skin rashes [Stevens-Johnson syndrome, dermatitis bullous (Not known), dermatitis exfoliative (Not known), toxic epidermal necrolysis (Rare)] 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.
- severe potentially fatal allergic condition (drug reaction with eosinophilia and systemic symptoms) that can involve the skin and most importantly other organs under the skin such as the kidney and the liver (Not known).
- a skin condition (acute generalised exanthematous pustulosis) accompanied by fever, which consists of numerous tiny fluid filled blisters contained within large areas of swollen and reddened skin (Not known)
- allergic reaction and severe allergic reaction (Not known)
- swelling of the face, lips, tongue or other parts of the body (Not known)
- shortness of breath, wheezing or trouble breathing (Not known)
- severe rash or hives (Uncommon), itching or rash on the skin (Common)
- yellowing of the eyes or skin (Not known)
- damage to blood cells [the signs include: being breathless when you do not expect it, red or brown urine (Not known), nosebleeds (Rare) and small spot bruising (Not known)], severe decrease in white blood cells [agranulocytosis (Rare)]
- severe or persistent diarrhoea accompanied by a fever or weakness (Rare)

If any of **the following** side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or other healthcare professional.

**Very common side effects** (may affect more than 1 in 10 people):

- diarrhoea

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

- yeast infection

- decrease in platelets, decrease of red blood cells or blood pigment/ haemoglobin, abnormal lab test (positive direct Coombs), prolonged blood clotting time (activated partial thromboplastin time prolonged)
- decrease in blood protein
- headache, sleeplessness
- abdominal pain, vomiting, nausea, constipation, upset stomach
- increase in blood liver enzymes
- abnormal kidney blood tests
- fever, injection site reaction

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

- decrease in white blood cells (leukopenia), prolonged blood clotting time (prothrombin time prolonged)
- decreased blood potassium, decreased blood sugar
- low blood pressure, inflammation of the veins (felt as tenderness or redness in the affected area), reddening of the skin
- increase of a blood pigment breakdown product (bilirubin)
- skin reactions with redness, formation of skin lesions, nettle rash
- joint and muscle pain
- chills

**Rare side effects** (may affect up to 1 in 1,000 people):

- inflammation of the mucous lining of the mouth

**Not known** (cannot be estimated from the available data) **side effects:**

- severe decrease of red blood cells, white blood cells and platelets (pancytopenia), decrease in white blood cells (neutropenia), decrease of red blood cells due to premature breakdown or degradation, bleeding time prolonged, increase of platelets, increase of a specific type of white blood cells (eosinophilia)
- inflammation of the liver
- poor kidney functions and kidney problems
- a form of lung disease where eosinophils (a form of white blood cell) appear in the lung in increased numbers.

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. You can also report side effects directly via HPR

Pharmacovigilance

Earlsfort Terrace

IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: <http://www.hpra.ie/>

Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion**

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 label after "EXP".

The expiry date refers to the last day of that month.

Unopened vials: This medicinal product does not require any special temperature storage conditions.

Keep the vials in the outer carton.

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 4 g/0.5 g powder for solution for infusion contains**

- The active substances are piperacillin and tazobactam.
- Each vial contains 4 g piperacillin (as sodium salt) and 0.5 g tazobactam (as sodium salt).
- There are no other ingredients.

### **What Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion looks like and contents of the pack**

Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion is a white to off-white powder for solution for infusion packaged in glass vials  
Packs containing 1 or 12 vials.

### **Marketing Authorisation Holder and Manufacturer:**

Hospira UK Limited  
Horizon, Honey Lane, Hurley  
Maidenhead  
SL6 6RJ  
United Kingdom

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

**Austria:** Piperacillin/Tazobactam 4 g/0,5 g Pulver zur Herstellung einer Infusionslösung

**Denmark:** "Piptazira" 4 g/0.5 g

**Finland:** Piperacillin/Tazobactam Hospira 4 g/0,5 g Infuusiokuiva-aine, liuosta varten

**France:** Pipéracilline-Tazobactam Hospira 4 g/500 mg, poudre pour solution pour perfusion

**Ireland :** Piperacillin/Tazobactam 4 g /0.5 g powder for solution for infusion

**Netherlands:** Piperacilline/Tazobactam Hospira 4000 mg/500 mg, poeder voor oplossing voor infusie

**Norway:** Piptazira

**Portugal:** Piperacilina +Tazobactam Pfizer 4 g/0.5 gPó para solução para

**Spain:** Piperacilina/Tazobactam Hospira 4 g/0,5 g polvo para solución para perfusion EFG

**Sweden:** Piperacillin/Tazobactam Hospira 4 g/0,5 g Pulver till infusionsvätska, lösning

**United Kingdom:** Piperacillin/Tazobactam 4 g /0.5 g powder for solution for infusion

**This leaflet was last revised in 12/2017.**

Ref: gxPP 3\_0 IE

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

***Instructions for use***

Piperacillin/tazobactam 4 g / 0.5 g is administered by intravenous infusion (over 30 minutes).

***Intravenous use***

Reconstitute each vial with one of the compatible solvents for reconstitution. Swirl until dissolved (for details on handling, please see below).

Content of vial	Volume of solvent* to be added to vial
4 g / 0.5 g (4 g piperacillin and 0.5 g tazobactam)	20 ml

\*Compatible solvents for reconstitution:

- 0.9% (9 mg/ml) sodium chloride solution for injection
- sterile water for injection<sup>(1)</sup>
- Glucose 5%

<sup>(1)</sup>Maximum recommended volume of sterile water for injection per dose is 50 ml

The reconstituted solution should be withdrawn from the vial by a syringe. When reconstituted as directed, the vial contents withdrawn by syringe will provide the labelled amount of piperacillin and tazobactam.

The reconstituted solution may be further diluted to desired volume (e.g. 50 ml to 150 ml) with out of the following compatible solvents:

- 0.9% (9 mg/ml) sodium chloride solution for injection
- Glucose 5%

This medicinal product must not be mixed with other medicinal products except those mentioned in above.

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

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

Piperacillin/tazobactam should be administered through an infusion set separately from any other drugs unless compatibility is proven.

Due to chemical instability, piperacillin/tazobactam should not be used in solutions containing only sodium bicarbonate.

Lactated Ringer's solution is not compatible with piperacillin/tazobactam.

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

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