

PACKAGE LEAFLET

Package leaflet: Information for the user

Piperacillin/Tazobactam 4 g/0.5 g powder and solvent for solution for infusion

Piperacillin/Tazobactam

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.
- 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 is and what it is used for
2. What you need to know before you are given 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 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 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 are given Piperacillin/Tazobactam

You must not be given Piperacillin/Tazobactam if:

- you are allergic (hypersensitive) to piperacillin or tazobactam or any of the other ingredients of this medicine (listed in section 6).
- you are allergic (hypersensitive) to other antibiotics such as penicillins, cephalosporins, or other beta-lactamase inhibitors as you may also be allergic to Piperacillin/Tazobactam.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking 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.

- 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.
- 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.
- 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.
- you are taking another antibiotic called vancomycin at the same time as Piperacillin/Tazobactam this may increase the risk of kidney injury (see also **Other medicines and Piperacillin/Tazobactam** in this leaflet).
- 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.
- you develop convulsions during the treatment. In this case, you should inform your doctor or other healthcare professional.
- you think you developed a new or worsening infection. In this case, you should inform your doctor or other healthcare professional.

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.

Children

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, pharmacist or nurse 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 (eg, tablets enhancing urination or some medicines for cancer).
- medicines containing the other antibiotics tobramycin, gentamicin or vancomycin. Tell your doctor if you have kidney problems. Taking Piperacillin/Tazobactam and vancomycin at the same time may increase the risk of kidney injury even if you have no kidney problems.

Effect on laboratory tests

Tell the doctor or laboratory staff that you are taking Piperacillin/Tazobactam 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 taking this medicine. Your doctor will decide if Piperacillin/Tazobactam 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 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.

Piperacillin/Tazobactam contains sodium

This medicinal product contains 459.7 mg sodium (main component of cooking/table salt) per bag. This is equivalent to 22.98 % of the recommended maximum daily dietary intake of sodium for an adult.

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

3. How to use Piperacillin/Tazobactam

Your doctor or other healthcare professional will give you this medicine through an infusion into one of your veins.

Dosage

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 above 12 years of age

The usual dose is 4 g/0.5 g of 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 each individual 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 receive 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 forget to use 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 nurse.

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:

The serious side effects (with frequency in brackets) 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.
- 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.
- 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 (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: may affect more than 1 in 10 people

- diarrhoea

Common: 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
- skin rash, itching
- abnormal kidney blood tests
- fever, injection site reaction

Uncommon: 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
- fits (convulsions), seen in patients on high doses or with kidney problems

- low blood pressure, inflammation of the veins (felt as tenderness or redness in the affected area), reddening of 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: may affect up to 1 in 1,000 people

- severe decrease in white blood cells (agranulocytosis), bleeding of the nose
- serious infection of the colon, inflammation of the mucous lining of the mouth
- detachment of the top layer of the skin all over the body (toxic epidermal necrolysis)

Not known: frequency cannot be estimated from the available data

- 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, small spot bruising, bleeding time prolonged, increase of platelets, increase of a specific type of white blood cells (eosinophilia)
- allergic reaction and severe allergic reaction
- inflammation of the liver, yellow staining of the skin or whites of the eyes
- serious body wide allergic reaction with skin and mucous lining rashes, blistering and various skin eruptions (Stevens-Johnson Syndrome), severe allergic condition involving skin and other organs such as the kidney and the liver (drug reaction with eosinophilia and systemic symptoms), numerous tiny fluid filled blisters contained within large areas of swollen and reddened skin accompanied by fever (acute generalised exanthematous pustulosis), skin reactions with blistering (dermatitis bullous)
- 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
- acute disorientation and confusion (delirium)

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

Beta-lactam antibiotics, including piperacillin/tazobactam, may lead to signs of altered brain function (encephalopathy) and convulsions.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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

This medicinal product does not require any special storage conditions regarding temperature.

The time interval between the beginning of reconstitution and the end of intravenous infusion should not exceed:

- 24 hours when stored at room temperature (25 °C)
- 7 days when stored under refrigerated conditions (2 – 8 °C)

From a microbiological point of view, unless the method of opening and reconstitution precludes the risk of microbial contamination, the product should be used immediately.

The reconstituted drug product is intended for single use only.
Do not freeze the reconstituted solution.

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 protect the environment

6. Contents of the pack and other information

What Piperacillin/Tazobactam contains

- The active substances are piperacillin and tazobactam.
One two-chamber bag contains piperacillin (as sodium salt) equivalent to 4 g and tazobactam (as sodium salt) equivalent to 0.5 g.
- The other ingredients are sodium chloride, sodium citrate dihydrate, disodium edetate dihydrate and water for injections.

What Piperacillin/Tazobactam looks like and contents of the pack

Piperacillin/Tazobactam is provided in colourless multilayer plastic two-chamber bags with a set-port. One side is opaque, the other side is transparent.

Before reconstitution, Piperacillin/Tazobactam contains a white to off white powder in one chamber and 100 ml of a clear and colourless sodium chloride solution (0.45 %) in the other chamber.
After reconstitution, the chamber contains a clear and colourless solution for infusion.

Piperacillin/Tazobactam is supplied as packs containing 24 two-chamber bags.

Marketing Authorisation Holder and Manufacturer

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Postal address:
34209 Melsungen
Germany

Phone: +49-5661-71-0
Fax: +49-5661-71-4567

Manufacturer

ACS DOBFAR S.p.A.
Via Enzo Ferrari SNC
Zona Industriale Villa Zaccheo
64020 Castellalto (TE)
Italy

This leaflet was last revised in 04/2026

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

Note: Use for bacteraemia due to extended-beta-lactamase (ESBL) producing *E. coli* and *K. pneumoniae* (ceftriaxone non-susceptible) is not recommended in adult patients.

Posology

The dose and frequency of Piperacillin/Tazobactam depends on the severity and localisation of the infection and expected pathogens.

Adult and adolescent patients

Infections

The usual dose is 4 g piperacillin/0.5 g tazobactam given every 8 hours.

For nosocomial pneumonia and bacterial infections in neutropenic patients, the recommended dose is 4 g piperacillin/0.5 g tazobactam administered every 6 hours. This regimen may also be applicable to treat patients with other indicated infections when particularly severe.

The following table summarises the treatment frequency and the recommended dose for adult and adolescent patients by indication or condition:

Treatment frequency	Piperacillin/Tazobactam
Every 6 hours	Severe pneumonia
	Neutropenic adults with fever suspected to be due to a bacterial infection
Every 8 hours	Complicated urinary tract infections (including pyelonephritis)
	Complicated intra-abdominal infections
	Skin and soft tissue infections (including diabetic foot infections)

Patients with renal impairment

The intravenous dose should be adjusted to the degree of actual renal impairment as follows (each patient must be monitored closely for signs of substance toxicity; medicinal product dose and interval should be adjusted accordingly):

Creatinine clearance (ml/min)	Piperacillin/Tazobactam
> 40	No dose adjustment necessary
20 – 40	Maximum dose suggested: 4 g/0.5 g every 8 hours
< 20	Maximum dose suggested: 4 g/0.5 g every 12 hours

For patients on haemodialysis, one additional dose of piperacillin/tazobactam 2 g/0.25 g should be administered following each dialysis period, because haemodialysis removes 30 % – 50 % of piperacillin in 4 hours.

Patients with hepatic impairment

No dose adjustment is necessary.

Elderly patients

No dose adjustment is required for the elderly with normal renal function or creatinine clearance values above 40 ml/min.

Paediatric population (2 – 12 years of age)

Infections

The following table summarises the treatment frequency and the dose per body weight for paediatric patients 2 – 12 years of age by indication or condition:

Dose per weight and treatment frequency	Indication/condition
80 mg piperacillin/10 mg tazobactam per kg body weight every 6 hours	Neutropenic children with fever suspected to be due to bacterial infections*
100 mg piperacillin/12.5 mg tazobactam per kg body weight every 8 hours	Complicated intra-abdominal infections*

* Not to exceed the maximum 4 g/0.5 g per dose over 30 minutes.

Patients with renal impairment

The intravenous dose should be adjusted to the degree of actual renal impairment as follows (each patient must be monitored closely for signs of substance toxicity; medicinal product dose and interval should be adjusted accordingly):

Creatinine clearance (ml/min)	Piperacillin/Tazobactam (recommended dose)
> 50	No dose adjustment needed.
≤ 50	70 mg piperacillin/8.75 mg tazobactam per kg body weight every 8 hours.

For children on haemodialysis, one additional dose of 40 mg piperacillin/5 mg tazobactam per kg body weight should be administered following each dialysis period.

Children aged below 2 years

The safety and efficacy of Piperacillin/Tazobactam in children 0 – 2 years of age has not been established.

No data from controlled clinical studies are available.

Treatment duration

The usual duration of treatment for most indications is in the range of 5 – 14 days. However, the duration of treatment should be guided by the severity of the infection, the pathogen(s) and the patient's clinical and bacteriological progress.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life after reconstitution

The reconstituted drug product is intended for single use only.

Shelf life after first opening

The opened two-chamber bag should be used immediately.

Special precautions for disposal and other handling

Do not cover any portion of foil strip with patient label.

Do not use in series connection.

Discard unit if foil strip of container is damaged.

Peel foil strip only when ready for use.

Visually inspect medicinal product prior to reconstitution. The solution should only be used if it is clear, colourless and practically free from particles.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instructions for giving Piperacillin/Tazobactam to yourself or someone else at home

Some patients, parents and carers are trained to give Piperacillin/Tazobactam at home.

Warning – You should only give this medicine to yourself or someone else at home after a doctor or nurse has trained you.

Instructions for reconstitution of the Piperacillin/Tazobactam two-chamber bag

1. Peel stickers halfway off and unfold container (fig. 1).
2. Peel foil strip from drug powder chamber (fig. 2).
3. Fold container just below diluent meniscus and squeeze until seal between diluent and powder pops open (fig. 3).
4. Shake the diluent-powder mixture until the drug powder is completely dissolved.
5. Visually inspect the reconstituted solution for particulate matter. Do not use unless the solution is clear, colourless and practically free from particles.
6. Squeeze folded container just below the solution meniscus to pop the second seal and release liquid into the port (fig. 4).
7. Remove foil tab cover from set port and attach sterile administration set (fig. 5). Hang bag on IV pole for administration of the whole dose, or only a fraction of it (e.g. for children).

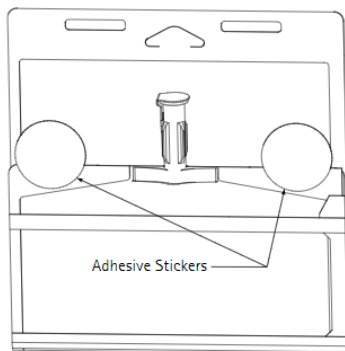


fig. 1

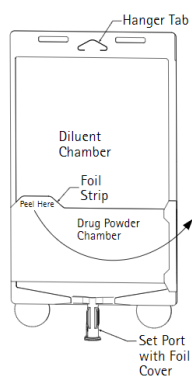


fig. 2

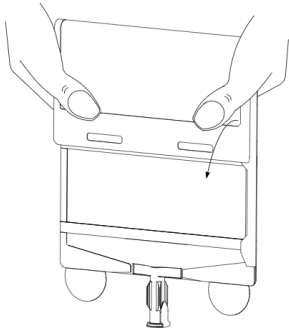


fig. 3

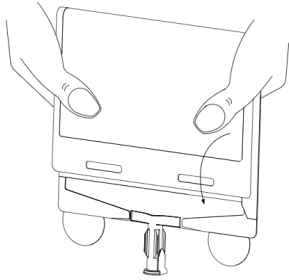


fig. 4

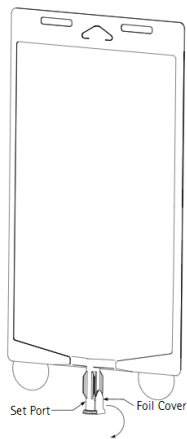


fig. 5

Co-administration with aminoglycosides

Due to the *in vitro* inactivation of the aminoglycoside by beta-lactam antibiotics, Piperacillin/Tazobactam and the aminoglycoside are recommended for separate administration.

In circumstances where co-administration is recommended, Piperacillin/Tazobactam is compatible for simultaneous co-administration via Y-site infusion only with the following aminoglycosides under the following conditions:

Aminoglycoside	Piperacillin and Tazobactam Dose	Piperacillin and Tazobactam Diluent Volume	Aminoglycoside Concentration Range	Acceptable Diluents for Aminoglycosides
Amikacin	4.5 g	100 ml	1.75 – 7.5 mg/ml	0.9 % sodium chloride or 5 % dextrose
Gentamicin	4.5 g	100 ml	0.7 – 3.32 mg/ml	0.9 % sodium chloride or 5 % dextrose

The mixed solutions can be stable up to 4 hours when stored at 25 °C with Amikacin, whereas it can be stable up to 60 minutes when stored at 25 °C with Gentamicin.