

Package leaflet: Information for the user

Piperacillin/Tazobactam Actavis 2 g / 0.25 g powder for solution for infusion
Piperacillin/Tazobactam Actavis 4 g / 0.5 g powder 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 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Piperacillin/Tazobactam Actavis 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 Actavis 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 Actavis may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Piperacillin/Tazobactam Actavis 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 Actavis 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 Actavis in combination with other antibiotics.

2. What you need to know before you use Piperacillin/Tazobactam Actavis

Do not use Piperacillin/Tazobactam Actavis:

- 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 Actavis.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Piperacillin/Tazobactam Actavis

- 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 Actavis** 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

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 Actavis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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, gentamycin or vancomycin. Tell your doctor if you have kidney problems.

Effect on laboratory tests

Tell the doctor or laboratory staff that you are taking Piperacillin/Tazobactam Actavis 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if Piperacillin/Tazobactam

Actavis 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 Actavis is right for you.

Driving and using machines

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

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

Piperacillin/Tazobactam Actavis 2 g / 0.25 g contains 4.7 mmol (or 108 mg) of sodium.

Piperacillin/Tazobactam Actavis 4 g / 0.5 g contains 9.4 mmol (or 216 mg) of sodium.

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

3. How to use Piperacillin/Tazobactam Actavis

Your doctor or other healthcare professional will give you this medicine through an infusion (a drip for 30 minutes) 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 the daily dose will not exceed 4 g / 0.5 g of Piperacillin/Tazobactam Actavis.

You will be given Piperacillin/Tazobactam Actavis 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 Actavis 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 Actavis than you should

As you will receive Piperacillin/Tazobactam Actavis 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 Actavis

If you think you have not been given a dose of Piperacillin/Tazobactam Actavis, 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 Actavis 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).
- 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).

Other side effects

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 skin
- increase of a blood pigment breakdown product (bilirubin)
- skin reactions with redness, formation of skin lesions
- 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 side effects (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, 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
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Piperacillin/Tazobactam Actavis

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: Store in the original package in order to protect from light. Store below 25°C.

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 Actavis 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 Actavis looks like and contents of the pack

Powder for solution for infusion

White to off-white powder.

Piperacillin/Tazobactam Actavis is supplied in packs of 1 or 12 vials and enclosed in a carton with a package leaflet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last approved in 27 April 2018

The following information is intended for healthcare professionals only:

Instructions for use

Piperacillin/Tazobactam Actavis will be given by intravenous infusion (a drip for 30 minutes).

Intravenous use

Reconstitute each vial with the volume of solvent shown in the table below, using one of the compatible solvents for reconstitution. Swirl until dissolved. When swirled constantly, reconstitution generally occurs within 5 to 10 minutes (for details on handling, please see below).

Content of vial	Volume of solvent* to be added to vial
2 g / 0.25 g (2 g piperacillin and 0.25 g tazobactam)	10 ml
4 g / 0.50 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 injections
- Glucose 5%
- Glucose 5% in sodium chloride 0.9% (9 mg/ml) solution

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

- 0.9% (9 mg/ml) sodium chloride solution for injection
- Sterile water for injections
- Glucose 5%
- Glucose 5% in sodium chloride 0.9% (9 mg/ml) solution
- Dextran 6% in 0.9% sodium chloride

Incompatibilities

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

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

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

Because of chemical instability, Piperacillin/Tazobactam Actavis should not be used with solutions containing sodium bicarbonate.

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