Package leaflet: Information for the user

Piperacillin/Tazobaktam Eugia 2 g / 0.25 g powder for solution for infusion
Piperacillin/Tazobaktam Eugia 4 g / 0.5 g powder for solution for infusion
(piperacillin/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, 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/Tazobaktam Eugia 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/Tazobaktam Eugia 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/Tazobaktam Eugia may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Piperacillin/Tazobaktam Eugia 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/Tazobaktam Eugia 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/Tazobaktam Eugia in combination with other antibiotics.

2. What you need to know before you take Piperacillin/Tazobaktam Eugia

Do not use Piperacillin/Tazobaktam Eugia
- 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/Tazobaktam Eugia.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Piperacillin/Tazobaktam Eugia.

- 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 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/Tazobaktam Eugia** in this leaflet).
- if you are taking certain medicines (called anticoagulants) to avoid an excess of blood clotting (see also **Other medicines and Piperacillin/Tazobaktam Eugia** 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.

Haemophagocytic lymphohistiocytosis
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 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/Tazobaktam Eugia
Tell your doctor or pharmacist if you are taking, 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:

- 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, gentamycin 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/Tazobaktam Eugia if you have to provide a blood or urine sample.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this medicine. Your doctor will decide if Piperacillin/Tazobaktam Eugia 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/Tazobaktam Eugia is right for you.

Driving and using machines
The use of Piperacillin/Tazobaktam Eugia is not expected to affect the ability to drive or use machines.

Piperacillin/Tazobaktam Eugia contains sodium

Piperacillin/Tazobaktam Eugia 2g/0.25g

This medicinal product contains 108 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 5.4 % of the recommended maximum daily dietary intake of sodium for an adult.

Piperacillin/Tazobaktam Eugia 4g/0.5g
This medicinal product contains 216 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 10.8 % of the recommended maximum daily dietary intake of sodium for an adult. This should be taken into consideration for patients who are on a controlled sodium diet.

3. How to take Piperacillin/Tazobaktam Eugia

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.

Adults and adolescents aged 12 years or older
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).

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 indivudual dose will not exceed 4 g / 0.5 g of Piperacillin/Tazobaktam Eugia.

You will be given Piperacillin/Tazobaktam Eugia 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/Tazobaktam Eugia 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/Tazobaktam Eugia than you should
As you will receive Piperacillin/Tazobaktam Eugia 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/Tazobaktam Eugia
If you think you have not been given a dose of Piperacillin/Tazobaktam Eugia, 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 of Piperacillin/Tazobaktam Eugia.

The serious side effects (with frequency in brackets) of Piperacillin/Tazobaktam Eugia 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 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
- skin rash, itching
- 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
- 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 side effects (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 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, 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 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/Tazobaktam Eugia

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

Powder:

Unopened vials: Store below 25 °C.

For single use only.
Discard any unused solution.
The reconstituted / diluted solutions of drug product are physically compatible and chemically stable over a period of 24 hours at controlled room temperature (25°C) and 48 hours at 2-8°C.

From a microbiological point of view, the reconstituted and diluted solutions 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 at 2-8°C, unless reconstitution and dilution have taken place in controlled and validated aseptic conditions.

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/Tazobaktam Eugia contains

The active substances are piperacillin and tazobactam.

Each vial contains piperacillin sodium corresponding to 2 g piperacillin and tazobactam sodium corresponding to 0.25 g tazobactam.

Each vial contains piperacillin sodium corresponding to 4 g piperacillin and tazobactam sodium corresponding to 0.5 g tazobactam.

There are no other ingredients.

What Piperacillin/Tazobaktam Eugia looks like and contents of the pack

Powder for solution for infusion

White to off-white powder.

Piperacillin/Tazobaktam Eugia is supplied in packs of 1, 10 and 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 revised in 2026-04-22

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-suseptible), is not recommended in adult patients.

Piperacillin/Tazobaktam Eugia 2 g/0.25 g

Piperacillin/Tazobaktam Eugia4 g/0.5 g
powder for solution for infusion

This is an extract from the Summary of Product Characteristics to assist in the administration of Piperacillin/Tazobaktam Eugia. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the SPC.

For slow intravenous infusion.

Incompatibilities with diluents and other medicinal products

- LACTATED RINGER'S (HARTMAN'S) SOLUTION IS NOT COMPATIBLE WITH PIPERACILLIN / TAZOBACTAM AUROBINDO.
- WHEN USED CONCURENTLY WITH ANOTHER ANTIBIOTICS [E.G. AMINIGLYCOSIDES], PIPERACILLIN/TAZOBAKTAM EUGIA BE ADMINISTERED SEPARATELY. MIXING OF PIPERACILLIN/TAZOBAKTAM EUGIA WITH AN AMINOGLYCOSIDE IN VITRO CAN CAUSE INACTIVATION OF THE AMINOGLYCOSIDE.
- PIPERACILLIN/TAZOBAKTAM EUGIA SHOULD NOT BE MIXED WITH OTHER DRUGS IN A SYRINGE OR INFUSION BOTTLE SINCE COMPATIBILITY HAS NOT BEEN ESTABLISHED.
- DUE TO CHEMICAL INSTABILITY, PIPERACILLIN/TAZOBAKTAM EUGIA SHOULD NOT BE USED IN SOLUTION THAT CONTAIN SODIUM BICARBONATE.
- PIPERACILLIN/TAZOBAKTAM EUGIA SHOULD NOT BE ADDED TO BLOOD PRODUCTS OR ALBUMIN HYDROLYSATES.

INSTRUCTIONS FOR USE AND HANDLING AND DISPOSAL
The reconstitution/dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Instruction for inserting the needle into the rubber stopper:

In order to avoid a coring phenomenon of the plug, when inserting the needle into the rubber stopper, it is recommended to use a needle of outside diameter less than or equal to 0.8 mm for the reconstitution of the product.
Needle should be inserted only at the center of the rubber stopper, in vertical direction.

For single use only. Discard any unused solution.

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

Sterile diluents for preparation of the reconstituted solution:
• Sterile Water for Injection
• 9 mg/ml (0.9%) Sodium Chloride for Injection
• Dextrose 50 mg/ml (5%) in water
• Dextrose (5%) in 0.9% sodium chloride solution

Dilution directions (for intravenous infusion)
Each vial Piperacillin/Tazobaktam Eugia 2 g/0.25 g should be reconstituted with 10 ml of the above diluents.
Each vial Piperacillin/Tazobaktam Eugia 4 g/0.5 g should be reconstituted with 20 ml of the above diluents.

Swirl until dissolved.

The reconstituted solutions may be further diluted to the over the concentration range of 13.33/1.67mg/ml to 80/10mg/ml with following diluents.

- Sterile Water for Injection
- 9 mg/ml (0.9%) Sodium Chloride for Injection
- Dextrose 50 mg/ml (5%) in water
- Dextrose 5% in 0.9% Sodium chloride solution

SPECIAL PRECAUTIONS FOR STORAGE
Unopened vials: Store below 25°C.

The reconstituted / diluted solutions of drug product are physically compatible and chemically stable over a period of 24 hours at controlled room temperature (25°C) and 48 hours at 2-8°C.

From a microbiological point of view, the reconstituted and diluted solutions 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 at 2-8°C, unless reconstitution and dilution have taken place in controlled and validated aseptic conditions.