Package leaflet: Information for the user

Pipercin 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, 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 Pipercin 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.

Pipercin 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. Pipercin may be used to treat bacterial infections in patients with low white blood cell counts (reduced resistance to infections).

Pipercin 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. Pipercin 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 Pipercin in combination with other antibiotics.

2. What you need to know before you are given Pipercin

Do not use Pipercin
- 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 Pipercin.

Warnings and precautions

Talk to your doctor or nurse before you are given Pipercin
- 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 Pipercin, this may increase the risk of kidney injury (see also **Other medicines and Pipercin** in this leaflet).
- if you are taking certain medicines (called anticoagulants) to avoid an excess of blood clotting (see also **Other medicines and Pipercin** 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.

If you notice signs or symptoms of an allergic reaction along with chest pain, tell your doctor immediately. This may be a sign of a condition called Kounis syndrome.

If you notice unexplained muscle pain, tenderness or weakness and/or dark coloured urine, tell your doctor immediately. This may be a sign of muscle breakdown (called rhabdomyolysis) which may lead to kidney problems.

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 Pipercin
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, gentamicin or vancomycin. Tell your doctor if you have kidney problems. Taking Pipercin 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 Pipercin 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 Pipercin 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 Pipercin is right for you.

Driving and using machines
The use of Pipercin is not expected to affect the ability to drive or use machines.

Pipercin contains sodium
Pipercin 4 g / 0.5 g: This medicine 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.

The maximum recommended daily dose of this medicine contains 864 mg sodium (found in table salt). This is equivalent to 43.2 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need Pipercin on a daily basis for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How Pipercin is given

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.

You will be given Pipercin until the signs of infection have gone completely (5 to 14 days).

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).

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.

Patients with kidney problems
Your doctor may need to reduce the dose of Pipercin 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 are given more Pipercin than you should
As you will receive Pipercin 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 Pipercin
If you think you have not been given a dose of Pipercin, 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 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 red and swollen eyes (conjunctivitis). The rash may progress to widespread blistering or peeling of the skin and potentially may be life-threatening**.** These may be signs of Stevens-Johnson syndrome (Not known), dermatitis bullous (Not known), dermatitis exfoliative (Not known), or toxic epidermal necrolysis (Rare)
- a skin condition accompanied by fever, which consists of numerous tiny fluid filled blisters contained within large areas of swollen and reddened skin, known as acute generalised exanthematous pustulosis (Not known)
- 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)
- swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (allergic reactions including anaphylactic shock, Not known)
- sudden chest pain which may occur with an allergic reaction known as Kounis syndrome (Not known)
- severe rash or hives (Uncommon), itching or rash on the skin (Common)
- inflammation of the liver (hepatitis, Not known), yellow staining of the skin or whites of the eyes (jaundice, Not known)
- low levels of red blood cells (anaemia, Common), excessive breakdown of red blood cells which causes being breathless when you do not expect it, red or brown urine (haemolytic anaemia, Not known)
- low levels of platelets, which can lead to bleeding and bruising (thrombocytopenia, Common)
- low levels of white blood cells, which fight infection (leukopenia, Uncommon or neutropenia, Not
- known)
- very low levels of a type of white blood cell called granulocytes (agranulocytosis, Rare)
- high levels of platelets (thrombocytosis, Not known)
- high levels of a type of white blood cells called eosinophils (eosinophilia, Not known)
- low levels of all types of blood cells, including platelets (pancytopenia, Not known)
- severe or persistent diarrhoea accompanied by a fever or weakness (pseudomembranous colitis,
- Rare)
- decreased blood potassium (Uncommon)
- seizures (convulsions), seen in patients on high dose, or with kidney problems (Uncommon)
- intense muscle pain, tenderness or weakness (rhabdomyolysis, Not known)

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
- antibodies in the blood that attack red blood cells (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*):
- prolonged blood clotting time (prothrombin time prolonged), 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):*
- bleeding of the nose, inflammation of the mucous lining of the mouth

Not known side effects *(cannot be estimated from the available data):*
- small spot bruising, bleeding time prolonged
- blistering disease in which blisters form in the skin and mucous membranes (linear IgA disease)
- 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 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:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pipercin

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 vial label and carton after “EXP”. The expiry date refers to the last day of that month.

Unopened vials: Do not store above 25 °C.

Reconstituted/Diluted Product:
For storage conditions for the reconstituted/Diluted product see "The following information is intended for healthcare professionals only:" at the end of the package leaflet.

Do not throw away any medicines via wastewater. 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 Pipercin contains
Each vial contains 4 g piperacillin (as sodium salt) and 0.5 g tazobactam (as sodium salt).
There are no other ingredients.

What Pipercin looks like and contents of the pack
Pipercin is a white to off-white powder for solution for infusion packaged in glass vials, packed in cartons containing 1, 5, 10 or 12 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
Mitim S.r.l., Via cacciamali 36/38 25125 Bresia, Italy

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Norway:	Piperacillin/Tazobactam Stragen
Belgium:	Piperacilline/Tazobactam EG
Czech Republic:	Tazip
Denmark:	Piperacillin/Tazobactam Stragen
Finland:	Piperacillin/Tazobactam Stragen
Germany:	Piperacillin/Tazobactam Stragen Pulver zur Herstellung einer Infusionslösung
Ireland:	Pipercin
Luxembourg:	Piperacilline/Tazobactam EG
Portugal:	Piperacillina + Tazobactam Basi
Sweden:	Piperacillin/Tazobactam Stragen
Netherlands:	Piperacilline/Tazobactam Stragen
United Kingdom (Northern Ireland):	Piperacillin/Tazobactam

This leaflet was last revised in November 2025.

The following information is intended for healthcare professionals only:

Pipercin
Powder for solution for infusion

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

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.

Instructions for use
Pipercin will be given by intravenous infusion (a drip for 30 minutes).

Incompatibilities with diluents and other medicinal products
- Lactated Ringer's solution is not compatible with Pipercin.
- When used concurrently with another antibiotic (e.g. aminoglycosides), Pipercin must be administered separately. Mixing with an aminoglycoside in vitro can cause inactivation of the aminoglycoside.
- Pipercin should not be mixed with other drugs in a syringe or infusion bottle since compatibility has not been established.
- Pipercin should be administered through an infusion set separately from any other drugs unless compatibility is proven.
- Due to chemical instability, Pipercin should not be used in solutions that contain sodium bicarbonate.
- Pipercin should not be added to blood products or albumin hydrolysates.

Reconstitution directions
The reconstitution and dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and discolouration prior to administration. The solution should only be used if the solution is clear and free from particles.

Intravenous use
Reconstitute each vial with the volume of solvent shown in the table below, using one of the compatible solvents for reconstitution. To reconstitute, tap lightly the vial to loosen powder from the bottom and sides. Wet all of the internal surface of the vial with solvent whilst shaking continuously. Shake until the powder is dissolved, reconstitution generally occurs within 5 to 10 minutes (for details on handling, please see below).

Content of the 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
- Water for injections(1)
- Dextrose 5 %

(1) Maximum recommended volume of water for injection per dose is 50 mL.

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

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
- Dextrose 5 %

For single use only. Discard any unused solution.
Any unused product or waste material should be disposed of in accordance with local requirements.

SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25 °C.

After reconstitution, chemical and physical in-use stability has been demonstrated for 24 hours when stored in a refrigerator at 2 – 8 °C.

After reconstitution and dilution, chemical and physical in-use stability has been demonstrated for 48 hours when stored in a refrigerator at 2 – 8 °C.
From a microbiological point of view, once opened, the product 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 has taken place in controlled and validated aseptic conditions.