

Professional Information

SCHEDULING STATUS: **S4**

CURITAZ™ 4,5 Powder for solution for infusion

Piperacillin and Tazobactam

Read all of this leaflet carefully before you start using CURITAZ 4,5

- Keep this leaflet. You might need to read it again.
- If you have further questions, please ask your doctor, pharmacist nurse or other health care provider.
- CURITAZ 4,5 has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

What is in this leaflet

1. What CURITAZ 4,5 is and what it is used for
2. What you need to know before you are given CURITAZ 4,5
3. How to receive CURITAZ 4,5
4. Possible side effects
5. How to store CURITAZ 4,5
6. Contents of the pack and other information

1. What CURITAZ 4,5 is and what it is used for

CURITAZ 4,5 contains a penicillin antibiotic (piperacillin) and a beta-lactamase inhibitor (tazobactam), which are used to treat infections caused by bacteria. The beta-lactamase inhibitor is added to the penicillin to protect the penicillin from certain substances (enzymes) that will destroy the penicillin antibiotic before it can kill the bacteria.

CURITAZ 4,5 is indicated for the treatment of the following bacterial infections:

Adults:



Bacterial infections in neutropenic patients (patients with low levels of white blood cells), in combination with an aminoglycoside.

Community acquired pneumonia.

Intra-abdominal infections.

Skin and soft tissue infections.

Gynaecological infections.

Children:

CURITAZ 4,5 plus an aminoglycoside is indicated for bacterial infections in neutropenic patients (patients with low levels of white blood cells).

In hospitalised children aged 2 to 12 years, CURITAZ 4,5 is indicated for the treatment of serious intra-abdominal infections. It has not been evaluated in this indication for paediatric patients below the age of 2 years.

Your doctor has prescribed this medicine for your specific condition.

2. What you need to know before you are given CURITAZ 4,5

CURITAZ 4,5 should not be administered to you if:

- You are hypersensitive (allergic) to piperacillin, tazobactam or any of the other ingredients of CURITAZ 4,5 (listed in section 6).
- You have ever had any unusual or allergic reaction to any of the penicillins, cephalosporins, or beta-lactamase inhibitors or suffer from any other allergies.

Warnings and precautions

Take special care with CURITAZ 4,5

- If you have allergies or a history of allergies, such as asthma, eczema, hay fever, or hives.
- If you have allergic reactions involving the skin and mucous membranes, such as eyes, ears, inside the nose, mouth and lips.
- If you have any kidney or liver problems.
- If you have a history of bleeding problems.
- If you have cystic fibrosis, where the body produces very thick, sticky mucus.



- 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 develop convulsions during the treatment. In this case, you should inform your doctor or other healthcare professional.
- If you are pregnant, or breastfeeding your baby, you should check with your doctor first before taking this medicine.
- If you are taking another medicine called vancomycin at the same time as CURITAZ.
- If you are on a low-sodium diet or have kidney disorders.
- Your doctor may monitor your potassium levels while you are taking this medicine, to avoid having too low potassium levels in the blood.
- 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 CURITAZ 4,5

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines may interact with CURITAZ 4,5 when you take them together and may either cause additional side effects or may not work as well:

- Anticoagulants (blood-thinners, e.g., heparin).
- Methotrexate.
- Muscle relaxing medicines (eg. vecuronium).



- Medicine for gout (probenecid).
- 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 CURITAZ 4,5 if you have to provide a blood or urine sample for testing.

Not all medicine interactions are described in this leaflet. It is therefore very important that you tell your doctor or health care provider of all the other medicines you are currently taking.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

Piperacillin and tazobactam can pass to a baby in the womb or through breast milk. If you are pregnant or breastfeeding, your doctor will decide if CURITAZ 4,5 is right for you.

Driving and using machines

The use of CURITAZ 4,5 is not expected to affect the ability to drive or use machines.

CURITAZ 4,5 contains sodium

CURITAZ 4,5 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 receive CURITAZ 4,5

Your doctor will prescribe the exact dose required for your condition. The doctor or health care provider will administer the correct dose to you every 6 to 8 hours, by slow intravenous infusion.



You will not be expected to give yourself CURITAZ 4,5. It will be given to you by a person who is qualified to do so.

If you receive more CURITAZ 4,5 than you should

Since a health care provider will administer CURITAZ 4,5 he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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 CURITAZ 4,5

If you think you have not been given a dose of CURITAZ 4,5, tell your doctor or other health care provider immediately.

If you have any further questions on the use of this product, ask your doctor or health care provider.

4. Possible side effects

CURITAZ 4,5 can have side effects.

Not all side effects reported for CURITAZ 4,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CURITAZ 4,5, please consult your health care provider for advice.

If any of the following happens, stop taking CURITAZ 4,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe or persistent diarrhoea accompanied by a fever or weakness
- Puffiness or swelling around the face, lips, tongue or other parts of the body
- Shortness of breath, wheezing or trouble breathing
- Severe rash or hives, itching or rash on the skin
- Serious skin rashes (Stevens-Johnson syndrome, dermatitis bullous, dermatitis exfoliative, toxic epidermal necrolysis) 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

These are all very serious side effects. If you have them, you may have had a serious reaction to CURITAZ 4,5. You may need urgent medical attention or hospitalisation.

Frequent side effects:

- *Reduction in blood platelets causing unusual bruising or bleeding (thrombocytopenia)*
- *Decrease of red blood cells or blood pigment / haemoglobin (anaemia)*
- *Decrease of white blood cells or blood pigment / haemoglobin (leukopenia)*
- *Sleeplessness*
- Headache
- Diarrhoea (mild)
- Stomach pain
- Nausea
- Vomiting
- Constipation
- Indigestion
- Skin rash
- Itching
- Fever
- Redness or swelling at the site of injection
- Increase in blood liver enzymes
- Decrease in blood protein
- Abnormal lab test (positive direct Coombs)
- Abnormal kidney blood tests
- Prolonged blood clotting time (activated partial thromboplastin time prolonged)

Less frequent side effects:



- Yeast infection
- Decrease in white blood cells (leukopenia)
- Severe decrease in white blood cells (agranulocytosis)
- Low potassium levels in the blood (hypokalaemia)
- Convulsions (seizures)
- Low blood pressure
- Inflammation of the veins (felt as tenderness or redness in the affected area)
- Reddening of skin
- Nose bleeding
- Inflammation of the mucous lining of the mouth causing a sore mouth or tongue
- Skin reactions with redness, formation of skin lesions, nettle rash
- Red skin lesions, often with a purple centre (erythema multiforme)
- Blistering and peeling of the skin
- Joint pain
- Muscle pain
- Chills
- Blood sugar decreased
- Increase of a blood pigment breakdown product (bilirubin)
- Prolonged blood clotting time (prothrombin time prolonged)

The frequency of the following side effects are unknown:

- Low number of red and white blood cells and platelets in the blood (pancytopenia)
- Decrease in white blood cells (neutropenia)
- Increase of a specific type of white blood cells (eosinophilia)
- Decrease of red blood cells due to premature breakdown or degradation (haemolytic anaemia)
- Increase of platelets (thrombocytosis)
- Allergic reactions, skin rash, hives, itching, red, irritated eyes
- Yellow eyes or skin (jaundice)
- Inflammation of the liver



- 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
- Purple or red spots on the skin or mucus membranes (purpura)
- Low levels of a protein called albumin in the blood.
- Low blood sugar levels.
- Low levels of potassium in the blood.
- Feeling confused.
- Inflammation of the entire skin.
- Trouble in urinating
- Kidney problems
- Bleeding time prolonged

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

Piperacillin therapy may cause a brain disease called encephalopathy and convulsions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CURITAZ 4,5.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.



4. How to store CURITAZ 4,5

Dry powder: Store at or below 25 °C.

Reconstituted solution: Store for 24 hours at 2 to 8 °C.

Any unused solution must be discarded.

KEEP OUT OF THE REACH OF CHILDREN.

Do not use this medicine after the expiry date stated on the container.

Please return all unused medicine to your pharmacist for safe disposal.

5. Contents of the pack and other information

What CURITAZ 4,5 contains

Each CURITAZ 4,5 100 ml glass bottle contains piperacillin sodium equivalent to piperacillin 4 g and tazobactam sodium equivalent to tazobactam 500 mg.

CURITAZ 4,5 does not contain any other ingredients.

What CURITAZ 4,5 looks like and contents of the pack

CURITAZ 4,5 is a white to yellowish powder.

Ready-for-use solution: Clear colourless to yellowish solution free from fibres and particulate matter.

CURITAZ 4,5 is available in 100 ml clear glass bottles with grey bromobutyl rubber stoppers and plastic flip-off caps.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

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Access to the corresponding Professional Information

Not applicable.

