Patient Information Leaflet for CINOTAZ

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CINOTAZ 2 powder for solution for infusion

CINOTAZ 4 powder for solution for infusion

Piperacillin and tazobactum

Sugar free.

Read all of this leaflet carefully before CINOTAZ is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What CINOTAZ is and what it is used for

Piperacillin belongs to the group of medicines known as broad spectrum penicillin antibiotics. It kills many kinds of bacteria. Tazobactam can prevent some bacteria becoming resistant to the effects of piperacillin.

CINOTAZ is used to treat bacterial infections such as those affecting your chest, urinary tract, stomach or skin.

CINOTAZ may also be used with medicines known as aminoglycosides to treat infections in patients who are unable to fight infections normally.

2. What you need to know before CINOTAZ is administered to you

CINOTAZ should not be administered to you if:

- You are hypersensitive (allergic) to tazobactam or piperacillin or any of the ingredients of CINOTAZ (listed in section 6).
- You have had allergic reactions to antibiotics known as penicillins or cephalosporins, or to medicines called beta-lactamase inhibitors (ask your doctor if you are not sure).
- You have a history of allergies (hypersensitivity).

Warnings and precautions:

Tell your doctor or health care provider before being given CINOTAZ if:

- You have kidney or liver problems, or if you receive haemodialysis treatment. Your doctor may check how well your kidneys are working before giving you CINOTAZ and you may have regular checks while receiving CINOTAZ.
- You have low levels of potassium in your blood; your doctor may take a blood sample from time to time for testing.
- You are going to receive a general anaesthetic.

Take special care 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 health care provider immediately. Do not take any medicine for the diarrhoea without first checking with your doctor.
- Any unexpected bleeding occurs while you are receiving CINOTAZ. In this case, you should inform your doctor or other health care provider immediately.
- You develop convulsions during the treatment. In this case, you should inform your doctor or other health care provider.
- You think you developed a new or worsening infection. In this case, you should inform your doctor or other health care provider.

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 and adolescents:

CINOTAZ is not recommended for use in children in children below the age of 2 years.

Other medicines and CINOTAZ:

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

Please consult your doctor, pharmacist or other health care provider for advice, if you are using any of the following medication:

- Probenecid (gout medicine).
- Medicines to thin your blood or to treat blood clots (e.g. heparin, warfarin or aspirin).

- A medicine called methotrexate (medicine to treat cancer, arthritis or psoriasis).
- A muscle relaxant called vecuronium.

Tell your doctor or laboratory staff that you are taking CINOTAZ if you have to provide a blood or urine sample.

Not all the medicines that would interact with CINOTAZ are listed above, if you are using any other medicinal product tell your doctor.

Pregnancy and breastfeeding:

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 you are given CINOTAZ. Safety in pregnancy and breastfeeding has not been established**.** CINOTAZ should not be used if you are breastfeeding your baby.

Driving and using machines:

CINOTAZ is not likely to affect you being able to drive or use machinery. If you are feeling nauseous or have a headache after using CINOTAZ make sure you are well enough to drive or use machinery.

CINOTAZ contains sodium:

CINOTAZ 2 contains 128 mg sodium per vial. This is equivalent to 6,5 % of the recommended maximum daily dietary intake of sodium for an adult.
CINOTAZ 4 contains 256 mg sodium per vial. This is equivalent to 13 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How CINOTAZ will be administered

Do not share medicines prescribed for you with any other person.

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

Your doctor will give CINOTAZ to you through a drip into one of your veins.

If you have kidney or liver problems, your doctor may need to adjust the dose of CINOTAZ or how often it is given.

If you have the impression that the effect of CINOTAZ is too strong or too weak, talk to your doctor or pharmacist.

If you receive more CINOTAZ than you should:

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

If you missed a dose of CINOTAZ:

Since a health care provider will administer CINOTAZ, it is unlikely that the dose will be missed.

4. Possible side effects

CINOTAZ can have side effects. Not all side effects reported for CINOTAZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CINOTAZ, please consult your health care provider for advice.

If any of the following happens, stop receiving CINOTAZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty breathing.
- Rash or itching.

- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you experience severe, persistent bloody diarrhoea, accompanied by fever or weakness.
- Serious skin rashes, appearing as widespread redness of the skin, or severe peeling of the skin. Additional signs include ulcers in the mouth, throat, nose, extremities, genitals and conjunctivitis (red and swollen eyes).
- Severe, potentially fatal condition that can involve the skin and most importantly other organs un the skin such as the kidney and the liver. Symptoms include fever, extensive skin rash, facial swelling and enlarged lymph nodes.
- A skin condition accompanied by fever, which consists of numerous tiny fluid-filled blisters contained within large areas of swollen and reddened skin.
- Fits (seizures).
- Inflammation of the liver, causing yellowing of the skin or whites of the eyes.
- Poor kidney function and kidney problems, making it difficult passing urine and causing shortness of breath and swelling.
- Damage to blood cells (the signs include being breathless when you do not expect it, red or brown urine, nosebleeds and small spot bruising), severe decrease in white blood cells.
- Piperacillin as contained in CINOTAZ, has been associated with an increased incidence of fever and rash in cystic fibrosis patients.

These are all serious side effects. You may need urgent medical attention.

Tell our doctor if you notice any of the following.

Side effects frequently reported are:

- Diarrhoea.
- Skin rashes.
- Feeling or being sick.
- Constipation.
- Abdominal pain.
- Abnormal blood test results showing decrease of red blood cells.
- Abnormal laboratory test results (positive direct Coombs).
- Pain, swelling, warmth or redness around the site of injection.

Side effects reported less frequently:

- Yeast infection.
- Headache.
- Difficulty sleeping.
- Fever.
- Increased sweating.
- Muscle pain or weakness.
- Pain in the joints.
- Twitching.
- Tiredness.
- Dry or sore mouth.
- Mouth ulcers.
- Stomach pain or discomfort.
- Soft or loose stools.
- Agitation (being nervously excited and anxious).
- Confusion.
- Anxiety.
- Hallucination (seeing, hearing or feeling things that does not exist).
- Depression.

- A feeling of being cold (chills).

Side effects reported with an unknown frequency:

- Acute disorientation and confusion (delirium).

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 or pharmacist. You can also report side effects to SAHPRA via the "**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 CINOTAZ.

5. How to store CINOTAZ

Dry powder: Vials containing sterile dry powder should be stored at controlled room temperature. Store at or below 25 °C.

Reconstituted infusion solutions: Vials containing reconstituted solutions for intravenous and intramuscular use should be stored for not more than 12 hours at room temperature (at or below 25 °C) and not more than 24 hours under refrigeration (2 – 8 °C).

Diluted infusion solutions should be stored for not more than 12 hours at 25 °C and not more than 24 hours at 2 – 8 °C in IV bags or syringes. Unused solution should be discarded.

Do not use after the expiry date printed on the label of the vial.

All medicines should be safely disposed of.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What CINOTAZ contains:

CINOTAZ contains two active ingredients namely piperacillin sodium equivalent to piperacillin 2 g or 4 g and tazobactam sodium equivalent to tazobactam 250 mg or 500 mg, respectively.

There are no other ingredients contained in CINOTAZ.

What CINOTAZ looks like and contents of the pack:

White to off-white powder. Reconstituted solution: Clear colourless solution free from foreign particles.

CINOTAZ 2: 20 mL clear, colourless Type I glass vial with grey bromobutyl rubber stopper, silver aluminium seal and blue flip-off seal.

CINOTAZ 4: 30 mL clear, colourless Type I glass vial with grey bromobutyl rubber stopper, silver aluminium seal and white flip-off seal, or

50 mL clear, colourless Type I glass vial with grey bromobutyl rubber stopper, silver aluminium seal and yellow flip-off seal.

Holder of certificate of registration and manufacturer:

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark, Midrand 1685

South Africa

Tel: (011) 848 3050

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