PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TAZOCIN® 4 EF Injection

Piperacillin/Tazobactam

Sugar free

Read all of this leaflet carefully before you are given TAZOCIN 4 EF Injection

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TAZOCIN 4 EF 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 TAZOCIN 4 EF is and what it is used for
2. What you need to know before you use TAZOCIN 4 EF
3. How to use TAZOCIN 4 EF
4. Possible side effects
5. How to store TAZOCIN 4 EF
6. Contents of the pack and other information

1. What TAZOCIN 4 EF is and what it is used for

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

TAZOCIN 4 EF is used to treat bacterial infections such as those affecting your chest, abdomen, skin, uterus or

blood.

TAZOCIN 4 EF 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 you use TAZOCIN 4 EF

TAZOCIN 4 EF should not be administered to you:

- if you are hypersensitive (allergic) to piperacillin, tazobactam or any of the other ingredients of TAZOCIN 4 EF (listed in section 6).
- if have you 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).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have a history of allergies (hypersensitivity).
- if you have low levels of potassium in your blood or are taking diuretics (water tablets for heart problems or high blood pressure). Your doctor might take a blood sample from time to time for testing.
- if you have kidney problems, or if you are receiving haemodialysis treatment. Your doctor may check how well your kidneys are working before he gives you TAZOCIN 4 EF and you may have regular checks whilst taking your medicine.
- if you are on a low sodium diet as TAZOCIN 4 EF contains sodium.

Other medicines and TAZOCIN 4 EF

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

You should tell your doctor if you are taking any of the following medicines as some medicines can affect

the way TAZOCIN 4 EF works, or TAZOCIN 4 EF itself can reduce the effectiveness of other medicines taken at the same time:

- probenecid used to treat gout
- medicines to thin your blood or to treat blood clots (e.g. heparin, warfarin or aspirin)
- muscle relaxants (e.g. vecuronium) used in anaesthesia and intensive care unit
- methotrexate used to treat cancer, arthritis or psoriasis

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been demonstrated.

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 taking this medicine.

Driving and using machines

It is not always possible to predict to what extent TAZOCIN 4 EF may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TAZOCIN 4EF affects them.

TAZOCIN 4 EF contains sodium

Talk to your doctor or other health care provider if you need to take TAZOCIN 4 EF for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to receive TAZOCIN 4 EF

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

You will not be expected to give yourself TAZOCIN 4 EF injection. It will be given to you by a person who is qualified to do so. Your doctor or nurse will give you TAZOCIN 4 EF by slow injection (infusion) into a vein.

Your doctor will decide on the exact dose depending on the severity of your infection.

If you have kidney or liver problems, your doctor may need to adjust the dose of TAZOCIN 4 EF or how often it is given. Your doctor may also want to test your blood to make sure that your treatment is working.

Your doctor will tell you how long your treatment with TAZOCIN 4 EF will last.

If you have the impression that the effect of TAZOCIN 4 EF is too strong or too weak, tell your doctor or nurse.

If you are given more TAZOCIN 4 EF than you should

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

If you miss a dose of TAZOCIN 4 EF

Since a health care provider will administer TAZOCIN 4 EF, it is unlikely that the dose will be missed. If you think that you have missed a dose of treatment, tell a doctor or nurse at once.

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

TAZOCIN 4 EF can have side effects.

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

Tell your doctor, nurse or health care provider immediately if you experience

- persistent bloody diarrhoea
- a severe allergic reaction (seen as swelling of the face, lips, tongue and throat or extreme breathing difficulty)
- widespread redness of the skin
- severe peeling of the skin

Frequent side effects

- diarrhoea
- changes in the number of red or white blood cells, platelets or protein in your blood
- iron deficiency (anaemia)
- yeast infections (e.g. thrush)
- headache, insomnia (inability to sleep)
- abdominal pain, feeling or being sick, constipation, heartburn/indigestion
- increases in levels of liver enzymes, creatinine or urea in the blood
- skin rash, itchy skin
- fever, pain, swelling, warmth or redness around the site of injection

Less frequent side effects

- Decrease in the number of white blood cells, changes in blood clotting tests, nose bleeds
- Reduced levels of potassium or glucose, increased levels of bilirubin in the blood
- Low blood pressure, inflammation of the veins (phlebitis), hot flushes
- Allergic skin reaction, pale red, raised and itchy bumps on the skin (urticaria), small red bumps on the skin*, peeling of the top layer of the skin (toxic epidermal necrolysis)
- Pain in the joints, muscle pain or weakness
- Cold shivers

Other side effects

- bleeding under the skin, increase in bleeding time, anaemia caused by the breakdown of red blood cells
- infection of the colon, inflammation of the mouth
- hypersensitivity reaction
- yellow pigmentation of skin and eyes (jaundice), increase in liver enzymes, inflammation of the liver
- blisters on the skin, serious allergic reaction with skin and mucous lining rashes and various skin eruptions (Stevens-Johnson syndrome)
- changes in kidney function or kidney failure

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

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 TAZOCIN 4 EF.

5. How to store TAZOCIN 4 EF

- Store all medicines out of reach of children.
- The hospital pharmacy with ensure TAZOCIN 4 EF powder for injection is stored at or below 25 °C and is used before the expiry date printed on the label.
- Made up solutions prepared in sterile conditions may be stored for up to 24 hours at room temperature

(below 25 °C) or 48 hours in a refrigerator (2 - 8 °C).

6. Contents of the pack and other information

What TAZOCIN 4 EF contains

- The active substances are piperacillin and tazobactam. TAZOCIN 4 EF injection contains piperacillin sodium equivalent to piperacillin 4 g and tazobactam sodium equivalent to tazobactam 500 mg.
- The other ingredients are citric acid monohydrate, disodium edetate dihydrate (EDTA) and sodium hydrogen carbonate.

What TAZOCIN 4 EF looks like and contents of the pack

70 mL glass vials containing a white to off-white caked mass or powder.

Constituted solution: clear colourless to pale yellow liquid free from foreign matter.

TAZOCIN 4 EF is available as a white to off-white sterile, cryodesiccated powder of piperacillin and tazobactam as the sodium salts packaged in 70 mL glass vials.

Each 70 mL vial contains sterile piperacillin sodium equivalent to 4 grams and sterile tazobactam sodium equivalent to 500 milligrams.

Holder of Certificate of Registration

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