Product Name: ZERBAXA Lyophilised Powder for Solution for IV Infusion	Component: English Patient Information Leaflet Date Approved: 13 June 2022

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZERBAXA® Lyophilised Powder for Solution for IV Infusion

Active substance: ceftolozane and tazobactam

Sugar free

Read all of this leaflet carefully, before you are given ZERBAXA Lyophilised Powder for Solution for IV Infusion.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZERBAXA Lyophilised Powder for Solution for IV Infusion 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 ZERBAXA Lyophilised Powder for Solution for IV Infusion is and what it is used for

ZERBAXA is used in adults age 18 years or older to treat complicated infections within the abdomen, kidney and urinary system, and an infection of the lungs called “pneumonia”.

ZERBAXA contains 2 active substances:

- Ceftolozane (a “cephalosporin” antibiotic) kills certain bacteria that can cause infection.
- Tazobactam (a “beta-lactamase inhibitor”) binds to bacterial enzymes called beta-lactamases that break down antibiotics.

Both antibiotics work together to kill certain bacteria and treat the infection.

Antibacterial drugs, including ZERBAXA, should only be used to treat bacterial infections. They do not treat viral infections (e.g. the common cold). Bacteria can become resistant to antibiotics over time. Your doctor will decide if you should be given ZERBAXA to treat your infection.

2. What you need to know before you are given ZERBAXA Lyophilised Powder for Solution for IV Infusion

You should not be given ZERBAXA Lyophilised Powder for Solution for IV Infusion if you:

- are allergic to ceftolozane, tazobactam or any of the other ingredients of ZERBAXA.
- are allergic to medicines known as “cephalosporins”.
- have had a severe allergic reaction (e.g. severe skin peeling; swelling of the face, hands, feet, lips, tongue or throat; or difficulty swallowing or breathing) to certain other beta-lactam antibiotics (e.g. penicillins or carbapenems).

Warnings and precautions

Tell your doctor or healthcare provider before being given ZERBAXA Lyophilised Powder for Solution for IV Infusion:

- if you have kidney problems.
- if you know you are allergic to cephalosporins, penicillins or other antibiotics.
- if you have recently had diarrhoea or if you develop diarrhoea while receiving ZERBAXA.

Children

ZERBAXA should not be given to children under 18 years old because there is not enough information on use in this age group.

Other medicines and ZERBAXA Lyophilised Powder for Solution for IV Infusion

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

Know the medicines you take. Keep a list of them and show the list to your healthcare provider when you get a new medicine.

It is especially important to tell your doctor if you take the following:

- Probenecid (a medicine used to treat gout).

Probenecid may increase the time it takes for tazobactam to leave your body.

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 healthcare provider for advice before you are given ZERBAXA. Safe use during pregnancy has not been established.

Driving and using machines

ZERBAXA may have effects on the ability to drive and use machines. Dizziness may occur following use of ZERBAXA.

ZERBAXA Lyophilised Powder for Solution for IV Infusion contains sodium

ZERBAXA contains (11,5 mmoL) 265 mg of sodium per vial. This should be taken into consideration if you are a on a controlled-sodium diet.

3. How to use ZERBAXA Lyophilised Powder for Solution for IV Infusion

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

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

Instructions for use

The dose depends on the type of infection that you have, where the infection is in your body and how serious the infection is. Your doctor will decide on the dose that you need.

The recommended dose of ZERBAXA is 1,5 g (containing 1 g of ceftolozane and 0,5 g of tazobactam) or 3 g (2 g of ceftolozane and 1 g of tazobactam) every 8 hours, which is given into one of your veins (directly into the bloodstream) as an intravenous (IV) infusion over 1 hour.

Treatment with ZERBAXA normally lasts between 4 and 14 days, depending on the severity and location of the infection and on how your body responds to the treatment.

Patients with kidney problems

Your doctor may need to reduce the dose of ZERBAXA or decide how often ZERBAXA is given to you. Your doctor may also want to test your blood to make sure you receive an appropriate dose.

Your doctor will tell you how long your treatment with ZERBAXA will last. Do not stop treatment early, unless instructed to do so by your doctor.

If you are given more ZERBAXA Lyophilised Powder for Solution for IV Infusion than you should

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

If you miss a dose of ZERBAXA Lyophilised Powder for Solution for IV Infusion

Since a healthcare provider will administer ZERBAXA, it is unlikely that the dose will be missed. If you think you have not been given a dose of ZERBAXA, tell your doctor or other healthcare provider immediately.

Effects when treatment with ZERBAXA Lyophilised Powder for Solution for IV Infusion is stopped

ZERBAXA should be administered exactly as directed. Missing doses or not completing the full course of therapy may lead to worsening of your symptoms. Incorrect use of ZERBAXA may increase the likelihood that bacteria will develop resistance and will not be treatable by ZERBAXA or other antibacterials in the future.

If you have any further questions on the use of this medicine, ask your doctor or other healthcare professional.

4. Possible side effects

ZERBAXA can have side effects.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZERBAXA. 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:

- chest pain
- angina
- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing
- signs of recurrent infections such as fever or sore throat
- less urine than is normal for you
- yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems.

Not all side effects reported for ZERBAXA are included in this leaflet. Should your general health worsen or if you experience any untoward effects, while using ZERBAXA, please consult your healthcare provider for advice.

Patients treated for complicated bacterial infections within the abdomen and urinary tract system

Tell your doctor if you notice any of the following:

Frequent side effects include:

- headache
- stomach ache
- constipation
- diarrhoea
- nausea
- vomiting
- increase in liver enzymes (from blood tests)
- rash
- fever (high temperature)
- decrease in blood pressure
- decrease in potassium (from blood tests)
- increase in the number of certain types of blood cells known as platelets
- dizziness
- anxiety

- difficulty sleeping
- local problems (e.g. abnormal redness of the skin, inflammation, pain, itching or rash) when putting a substance into a vein (infusion site reactions).

Less frequent side effects include:

- inflammation of the large intestine due to *C. difficile* bacteria
- inflammation of the stomach
- abdominal bloating
- indigestion
- excessive gas in stomach or bowel
- obstruction of the intestine
- yeast infection in the mouth (thrush)
- yeast infection of female genitalia
- fungal urinary tract infection
- increase in sugar (glucose) levels (from blood tests)
- decrease in magnesium levels (from blood tests)
- decrease in phosphate levels (from blood tests)
- ischaemic stroke (stroke caused by reduced blood flow in brain)
- venous thrombosis (blood clot in a vein)
- low red blood cell counts
- atrial fibrillation (a condition involving rapid, irregular heartbeat)
- fast heartbeat

- angina pectoris (chest pain or feeling of tightness, pressure or heaviness in chest)
- itchy rash or swelling on the skin (hives)
- kidney problems
- kidney disease
- shortness of breath
- Coombs test positive (a blood test that looks for antibodies that may fight against your red blood cells.

Patients treated for hospital acquired bacterial pneumonia

Frequent side effects include:

- inflammation of the large intestine due to *C. difficile* bacteria
- diarrhoea
- vomiting
- increase in liver enzymes (from blood tests).

Less-frequent side effects include:

- infection due to *C. difficile* bacteria
- *C. difficile* test positive (from stool test)
- Coombs test positive (a blood test that looks for antibodies that may fight against your red blood cells).

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

Other side effects may also occur. Some side effects may be serious.

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 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 ZERBAXA.

5. How to store ZERBAXA Lyophilised Powder for Solution for IV Infusion

ZERBAXA vials should be stored in a refrigerator (2 to 8 °C).

Store in the original container. Protect from light.

Do not freeze. For single use only. Discard any unused portion.

Store all medicines out of the reach of children.

Do not use after the expiry date stated on the label.

6. Contents of the pack and other information

What ZERBAXA Lyophilised Powder for Solution for IV Infusion contains

The active substance is ceftolozane 1 g and tazobactam 0,5 g.

Each vial contains 11,5 mmoL (265 mg) of sodium.

The other ingredients are sodium chloride, citric acid and L-arginine.

What ZERBAXA Lyophilised Powder for Solution for IV Infusion looks like and contents of the pack

ZERBAXA for injection is a white to yellow sterile lyophilised powder for solution for IV infusion.

Reconstituted solution: ZERBAXA solution for infusion is clear and colourless to slightly yellow, free from visible particles.

ZERBAXA is available in a 20 mL clear glass vial with a siliconized stopper and sealed with a purple, aluminium and plastic flip-off seal.

Outer carton: The 20 mL vial is packed in a cardboard carton with the professional information and patient information leaflet.

Pack size of 1 or 10 vials.

Not all pack sizes may be marketed.

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