

ZERBAXA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given ZERBAXA?

ZERBAXA contains two active ingredients Ceftolozane and Tazobactam. ZERBAXA is used to treat complicated abdominal and urinary system infections and Nosocomial pneumonia.

For more information, see Section [1. Why am I being given ZERBAXA?](#) in the full CMI.

2. What should I know before I am given ZERBAXA?

Do not use if you have ever had an allergic reaction to ZERBAXA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given ZERBAXA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZERBAXA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given ZERBAXA?

The recommended 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 or other healthcare professional will give you this medicine through an infusion (a drip for 1 hour) into one of your veins.

More instructions can be found in Section [4. How am I given ZERBAXA?](#) in the full CMI.

5. What should I know while being given ZERBAXA?

Things you should do	
	<ul style="list-style-type: none">● If you develop diarrhoea whilst being given ZERBAXA, tell your doctor immediately. Do this even if it occurs

	<p>several weeks after stopping ZERBAXA.</p> <ul style="list-style-type: none"> • This may be a sign of a serious side effect that affects the bowel. You may need urgent medical care.
Looking after your medicine	<ul style="list-style-type: none"> • ZERBAXA will be stored in the pharmacy or on the ward. • ZERBAXA is stored in its original packaging in a refrigerator between 2 and 8 degrees Celsius.

For more information, see Section [5. What should I know while being given ZERBAXA?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, ZERBAXA can cause side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given ZERBAXA.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZERBAXA®

Active ingredients: *ceftolozane and tazobactam*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZERBAXA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZERBAXA.**

Where to find information in this leaflet:

- [1. Why am I being given ZERBAXA?](#)
- [2. What should I know before I am given ZERBAXA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given ZERBAXA?](#)
- [5. What should I know while being given ZERBAXA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given ZERBAXA?

ZERBAXA contains two active ingredients:

Ceftolozane, an antibiotic that belongs to the group of "cephalosporins". Ceftolozane can kill many kinds of bacteria that can cause infection.

Tazobactam belongs to the group of medicines known as “beta-lactamase inhibitors”. Tazobactam can help ceftolozane work against some resistant types of bacteria.

When ceftolozane and tazobactam are given together, more types of bacteria are killed.

ZERBAXA is used in adults and children (birth to less than 18 years of age) to treat:

- Complicated abdominal and urinary system infections, including a condition called pyelonephritis.

ZERBAXA is an antibiotic prescribed to treat adults aged 18 years or older with:

- Nosocomial pneumonia (an infection of the lungs that can occur while in the hospital or in recently hospitalized patients), including a condition called “ventilator-associated pneumonia” (an infection of the lungs that can occur while on a respirator).

Your doctor may have prescribed ZERBAXA for another reason. Ask your doctor if you have any questions about why ZERBAXA has been prescribed for you.

2. What should I know before I am given ZERBAXA?

Warnings

Do not use ZERBAXA if:

- you are allergic to ceftolozane, tazobactam or any of the other ingredients of this medicine
- you are highly allergic to beta-lactam class antibiotics (such as penicillin), or medicines known as "cephalosporins" (e.g., cephalexin)

Some symptoms of an allergic reaction may include skin rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Check with your doctor if you:

- know you are, or have previously been hypersensitive to cephalosporins, penicillins or other antibacterial medicines.
- have recently had diarrhoea, or have had diarrhoea before taking this medicine.
- know you have difficulty fighting off infections, are receiving medicines to help fight infections, or have neutropenia (low white blood cell count).
- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will advise if you should receive ZERBAXA during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor will discuss the possible risks and benefits of using ZERBAXA while you are breast-feeding.

Children

ZERBAXA can be given to children from birth and older to treat complicated bacterial infections within the abdomen and urinary tract system, including a condition called "pyelonephritis" (a type of urinary tract infection that affects one or both kidneys).

Addiction

ZERBAXA is not addictive.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ZERBAXA may interfere with each other, including:

- probenecid (a medicine for gout)
- diclofenac (a medicine to treat pain and inflammation associated with arthritis)
- cimetidine (a medicine used to treat heartburn and stomach ulcers)

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

Some medicines may be affected by ZERBAXA or may affect how well it works. You may need different amounts of these medicines, or you may need to be given different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZERBAXA.

4. How am I given ZERBAXA?

How much is given

Adults

- The recommended 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 is one or two vials of ZERBAXA (containing 1000 mg of ceftolozane and 500 mg of tazobactam) every 8 hours, which is given into one of your veins (directly into the bloodstream).

Children

- The dose for children will be calculated by the doctor based on the weight of the child.

Patients with kidney problems

- Your doctor may need to reduce the dose of ZERBAXA 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. ZERBAXA should not be given to children with kidney problems.

How is ZERBAXA given

Your doctor or other healthcare professional will give you this medicine through an infusion (a drip for 1 hour) into one of your veins.

How long is ZERBAXA given for

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

Your doctor will determine when your treatment should be stopped.

If you are given too much ZERBAXA

As this product is administered by a doctor or healthcare professional, it is very unlikely that you will be given too much ZERBAXA. However, if you have any concerns, talk to your doctor or other health care professional.

If you think you have used too much ZERBAXA, you may need urgent medical attention. **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given ZERBAXA?

Call your doctor straight away if you:

- develop diarrhoea whilst being given ZERBAXA. Do this even if it occurs several weeks after stopping ZERBAXA.
- This may be a sign of a serious side effect that affects the bowel. You may need urgent medical care.

Remind any doctor, dentist or pharmacist you visit that you are using ZERBAXA.

Looking after your medicine

ZERBAXA will be stored in the pharmacy or on the ward.

ZERBAXA is stored in its original packaging in a refrigerator between 2 and 8 degrees Celsius.

Heat and light can destroy some medicines.

Getting rid of any unwanted medicine

Hospital staff will dispose of this medicine safely.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given ZERBAXA.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects for patients treated for complicated bacterial infections within the abdomen and urinary tract system

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Cardiac disorders: <ul style="list-style-type: none"> ○ Atrial fibrillation (a condition involving rapid or irregular heartbeat) ○ Chest pain or feeling of tightness, pressure or heaviness in chest (angina pectoris) ○ Fast heartbeat ● Gastrointestinal disorders: <ul style="list-style-type: none"> ○ Abdominal bloating ○ Constipation ○ Diarrhoea ○ Excessive gas in stomach or bowel ○ Indigestion ○ Inflammation of the stomach ● General disorders and administration site conditions: 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ○ Anxiety ○ Dizziness ○ Insomnia ○ Itchy rash or swelling on the skin (hives) ○ Local problems (e.g., abnormal redness of the skin, inflammation, pain, itching, or rash) when putting a substance into a vein (infusion site reactions) ○ Vomiting ● Infections and infestations: <ul style="list-style-type: none"> ○ Yeast infection of female genitalia ○ Yeast infection in the mouth (thrush) ● Investigations: <ul style="list-style-type: none"> ○ Coombs test positive (a blood test that looks for antibodies that may fight against your red blood cells) ● Metabolism and nutrition disorders: 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ○ Decrease in magnesium levels (from blood tests) ○ Decrease in phosphate levels (from blood tests) ○ Decrease in potassium (from blood tests) ○ Increase in sugar (glucose) levels (from blood tests) ● Renal and urinary system: <ul style="list-style-type: none"> ○ Fungal urinary tract infection ● Respiratory, thoracic, and mediastinal disorders: <ul style="list-style-type: none"> ○ Shortness of breath ● Skin and subcutaneous tissue disorders: <ul style="list-style-type: none"> ○ Rash 	

Serious side effects for patients treated for complicated bacterial infections within the abdomen and urinary tract system

Serious side effects	What to do
<ul style="list-style-type: none"> ● Cardiac disorders: <ul style="list-style-type: none"> ○ Decrease in blood pressure ● Gastrointestinal disorders: <ul style="list-style-type: none"> ○ Abdominal pain (stomach ache) ● General disorders and administration site conditions: <ul style="list-style-type: none"> ○ Fever (high temperature) ○ Headache ○ Nausea ● Infections and infestations: <ul style="list-style-type: none"> ○ Inflammation of the large intestine due to C. difficile bacteria ● Investigations: <ul style="list-style-type: none"> ○ Increase in liver enzymes (from blood tests) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ○ Increase in number of certain types of blood cells known as platelets ● Metabolism and nutrition disorders: <ul style="list-style-type: none"> ○ Low red blood cell counts ● Nervous system disorders: <ul style="list-style-type: none"> ○ Ischemic stroke (stroke caused by reduced blood flow in brain) ● Vascular disorders: <ul style="list-style-type: none"> ○ Blood clot in a vein (venous thrombosis) ● Renal and urinary system: <ul style="list-style-type: none"> ○ Kidney problems ○ Kidney disease ○ Obstruction of the intestine 	

Less serious side effects for patients treated for nosocomial pneumonia

Less serious side effects	What to do
<ul style="list-style-type: none"> ● General disorders <ul style="list-style-type: none"> ○ Vomiting ● Infections and infestations: <ul style="list-style-type: none"> ○ C. difficile test positive (from stool test) ○ Infection due to C. difficile bacteria (diarrhoea and fever) ● Investigations: <ul style="list-style-type: none"> ○ Coombs test positive (a blood test that looks for antibodies that may fight against your red blood cells) ○ Increase in liver enzymes (from blood tests) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects for patients treated for nosocomial pneumonia

Serious side effects	What to do
<ul style="list-style-type: none">● Infections:<ul style="list-style-type: none">○ Inflammation of the large intestine due to C. difficile bacteria (abdominal pain, diarrhoea and fever)● Investigations:<ul style="list-style-type: none">○ Increase in liver enzymes (from blood tests)● Renal and urinary system:<ul style="list-style-type: none">○ Diarrhoea	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Additional nervous system side effects include:

- Seizures
- Twitching or jerking of muscles
- Feeling confused or agitated

Like all medicines, this medicine can cause side effects, although not everybody gets them.

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZERBAXA contains

Active ingredients (main ingredients)	Ceftolozane sulfate Tazobactam
Other ingredients	Citric acid

(inactive ingredients)	Sodium Chloride Arginine
-------------------------------	-----------------------------

Do not take this medicine if you are allergic to any of these ingredients.

What ZERBAXA looks like

ZERBAXA is a white to slightly yellow powder supplied in glass containers (vials).

The powder is mixed with sterile liquid to give a clear, colourless to yellow solution for infusion by your doctor (AUST R 229608).

Who distributes ZERBAXA

Merck Sharp and Dohme (Australia) Pty Ltd
Level 1, Building A, 26 Talavera Road
Macquarie Park NSW 2113 Australia

This leaflet was prepared in June 2024.

CCPPI-MK7625A-IV-092022

RCN: B000000887

Copyright © 2024 Merck & Co., Inc., Rahway, NJ, USA, and its affiliates. All rights reserved.