

ZERBAXA® Powder for Injection

ceftolozane and tazobactam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZERBAXA. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having ZERBAXA against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What ZERBAXA is used for

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 age 18 years or older to treat:

- Complicated abdominal and urinary system infections,

including a condition called pyelonephritis.

- 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.

ZERBAXA is only available with a doctor's prescription.

ZERBAXA is not addictive.

Before you are given ZERBAXA

When you must not be given it

Do not have ZERBAXA:

- if you are allergic to ceftolozane, tazobactam or any of the other ingredients of this medicine
- if 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.

Before you are given it

Tell your doctor:

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

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy 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.

If you have not told your doctor or pharmacist about any of the above, tell them before you receive ZERBAXA.

Use in children

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

How ZERBAXA is given

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).

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.

How is it 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 it 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 (overdose)

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 healthcare professional.

Whilst you are receiving ZERBAXA

Things you must do

If you develop diarrhoea whilst being given ZERBAXA, tell your doctor immediately. 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.

If you think you have not been given a dose of ZERBAXA, tell your doctor or other healthcare professional immediately.

Side effects

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

All medicines can have 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.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

For patients treated for complicated bacterial infections within the abdomen and urinary tract system, the more common side effects (may affect up to 1 in 10 people) include:

- Headache
- Abdominal pain (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 number of certain types of blood cells known as platelets
- Dizziness
- Anxiety
- Insomnia
- Local problems (e.g., abnormal redness of the skin, inflammation, pain, itching, or rash) when putting a substance into a vein (infusion site reactions)

Uncommon side effects (may affect up to 1 in 100 people) 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)
- Ischemic stroke (stroke caused by reduced blood flow in brain)
- Blood clot in a vein (venous thrombosis)
- Low red blood cell counts
- Atrial fibrillation (a condition involving rapid or irregular heartbeat)
- Fast heart beat
- Chest pain or feeling of tightness, pressure or heaviness in chest (angina pectoris)
- Coombs test positive (a blood test that looks for antibodies that may fight against your red blood cells)
- Itchy rash or swelling on the skin (hives)
- Kidney problems
- Kidney disease
- Shortness of breath

For patients treated for nosocomial pneumonia, the more common side effects (may affect up to 1 in 10 people) include:

- Inflammation of the large intestine due to *C. difficile* bacteria
- Diarrhea
- Vomiting
- Increase in liver enzymes (from blood tests)

Uncommon side effects (may affect up to 1 in 100 people) 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)

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 if you notice anything else that is making you feel unwell, even if it is not on this list.

After being given ZERBAXA

Storage

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

Disposal

Hospital staff will dispose of this medicine safely.

Product description

What does ZERBAXA Powder for Injection look 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.

Ingredients

Active ingredients

- Ceftolozane sulfate
- Tazobactam

Inactive ingredients

- Citric acid
- Sodium Chloride
- Arginine

Sponsor

Australian Sponsor

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Australian Registration Number:
229608

This leaflet was prepared in January 2024.

CCPPI-MK7625A-IV-112018
RCN000026625-AU