READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

ZERBAXA®

zer bax' ah

ceftolozane and tazobactam

Read this carefully before you start taking **ZERBAXA®**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZERBAXA®**.

Serious Warnings and Precautions

Severe and sometimes fatal allergic reactions (e.g. anaphylaxis) have occurred with beta-lactam antibiotics. Tell your doctor if you are allergic to antibacterial drugs such as penicillins, cephalosporin or carbapenem. If you have a severe allergic reaction, stop taking ZERBAXA® and get immediate medical attention (See What are the possible side effects).

What is ZERBAXA® used for?

ZERBAXA® is used by healthcare professionals to treat complicated infections within the abdominal cavity and urinary tract infections, including a condition called "pyelonephritis" (a type of urinary tract infection that affects one or both kidneys) in adults.

Antibacterial drugs like ZERBAXA® treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, ZERBAXA® should be taken exactly as directed. Misuse or overuse of ZERBAXA® could lead to the growth of bacteria that will not be killed by ZERBAXA® (resistance). This means that ZERBAXA® may not work for you in the future. Do not share your medicine.

How does ZERBAXA® work?

ZERBAXA® contains 2 active substances. Ceftolozane prevents the growth of the bacterial cell wall and tazobactam binds to bacterial enzymes (e.g. beta-lactamases) that breakdown the antibiotics. Both work together to kill bacteria and reduce the infection.

What are the ingredients in ZERBAXA®?

Medicinal ingredients: ceftolozane 1 g (as ceftolozane sulfate) and tazobactam 0.5 g (as tazobactam sodium) per vial.

Non-medicinal ingredients: citric acid, L-arginine, and sodium chloride

ZERBAXA® comes in the following dosage forms:
ZERBAXA® is available as a lyophilized powder injection for intravenous use.

Do not use ZERBAXA® if you are hypersensitive (allergic) to:
- this drug or to any ingredient listed above.
- antibiotics like penicillin, or medicines known as "cephalosporins", or other beta-lactams.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZERBAXA®. Talk about any health conditions or problems you may have, including if you:
- know you are, or have previously been hypersensitive to penicillins, cephalosporins, beta-lactamases, or other antibacterial medicines.
- have recently had diarrhea, or have had diarrhea before taking this medicine.
- have liver or kidney problems.
- are pregnant or planning to become pregnant. If you think you may be pregnant or are planning to have a baby, ask your healthcare professional or pharmacist for advice before taking this medicine.
- are breast-feeding or planning to breastfeed.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ZERBAXA®:
- Probenecid (a drug used to treat gout)

How to take ZERBAXA®:
The usual total daily dose of ZERBAXA® for adults is 1.5 g (1 g ceftolozane and 0.5 g tazobactam) administered every 8 hours by intravenous (IV) infusion over 1 hour, administered by the healthcare professional.

If you have kidney problems, your dose may be reduced.

Overdose:

If you think you have taken too much ZERBAXA®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
ZERBAXA® is usually administered by a healthcare professional. If you suspect a missed dose, talk to your healthcare professional.

What are possible side effects from using ZERBAXA®?
Like all medicines, ZERBAXA® may have side effects. The most common side effects (may affect up to 1 in 10 people) are:

- Increase in the number of certain types of blood cells known as platelets
- Anemia
- Decrease in potassium (from blood tests)
- Insomnia
- Anxiety
- Headache
- Dizziness
- Atrial fibrillation (abnormal heart rhythm)
- Decrease in blood pressure
- Nausea
- Diarrhea
- Constipation
- Vomiting
- Abdominal pain (stomach ache)
- Rash
- Fever (high temperature)
- Increased liver enzymes (from blood tests)
- 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) are:

- 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)
- Venous thrombosis (blood clot in a vein)
- Low red blood cell counts
- Atrial fibrillation (a condition involving rapid, irregular heartbeat)
- Fast heart beat
- 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

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have Clostridium difficile colitis (bowel inflammation). If this occurs, stop taking ZERBAXA® and contact your healthcare professional immediately.

These are not all the possible side effects you may feel when taking ZERBAXA®. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE **Allergic Reaction:** rash, hives (skin eruptions), swelling of the face, lips, tongue or throat, difficulty swallowing or breathing,			✓
Liver Disorder: yellowing of the skin or eyes, dark urine, pale stools		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhpmps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Unopened vials: Store in a refrigerator (2°C – 8°C).

Store in the original package in order to protect from light.

Keep out of reach and sight of children.

If you want more information about ZERBAXA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website or Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to ZERBAXA®, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

Last Revised: July 26, 2017