PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr] ZEVTERA®

Ceftobiprole for injection

Read this carefully before you start taking **ZEVTERA** and each time you get a refill. 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 **ZEVTERA**.

Serious Warnings and Precautions

- **Serious and occasionally fatal allergic (hypersensitivity) reactions and serious skin adverse reactions have been reported in patients receiving beta-lactam antibiotics (same class as ZEVTERA). Allergic reactions have also been observed with ZEVTERA use. Talk to your doctor if you have had any previous allergic reactions to penicillins, cephalosporins or other allergens (See What are possible side effects from using ZEVTERA).**

What is ZEVTERA used for?

ZEVTERA is used for the treatment of bacterial infections. Your doctor prescribed ZEVTERA because you have a serious lung infection referred to as Hospital-acquired pneumonia (HAP) or Community-acquired pneumonia (CAP).

Antibacterial drugs, including ZEVTERA, should only be used to treat bacterial infections. They do not treat viral infections (e.g. the common cold). Your doctor will make this decision. Although it is common to feel better early in the course of antibacterial therapy, the medication should be taken exactly as directed and should not be shared. Misuse or overuse of ZEVTERA could lead to the growth of bacteria that will not be killed by ZEVTERA (resistance). This means that ZEVTERA may not work for you in the future. Do not share your medicine.

How does ZEVTERA work?

ZEVTERA is an antibiotic medicine containing the active substance ceftobiprole, which belongs to an established group of medicines called ‘cephalosporin antibiotics’. ZEVTERA works by killing certain bacteria which can cause serious lung infections, including those which have developed resistance to other drugs.

What are the ingredients in ZEVTERA?

Medicinal ingredient: ceftobiprole, as ceftobiprole medocaril

Non-medicinal ingredients: citric acid monohydrate, sodium hydroxide

ZEVTERA comes in the following dosage forms:

ZEVTERA comes as a powder for solution in clear glass vials, each vial containing 500 mg of the active substance ceftobiprole. The powder is made up into a concentrate by a doctor or nurse, then diluted for intravenous administration.

Do not use ZEVTERA if:

- you are hypersensitive (allergic) to ZEVTERA or to citric acid monohydrate or sodium hydroxide.
- you are hypersensitive to cephalosporin antibiotics.
- you have immediate and severe hypersensitivity (e.g., an anaphylactic (severe allergic) reaction) to any other type of beta-lactam antibiotic, such as penicillins or carbapenems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZEVTERA. Talk about any health conditions or problems you may have, including if you:

- have other infections. While antibiotics including ZEVTERA kill certain bacteria, other bacteria and fungi may continue to grow more than normal. This is called overgrowth. Your doctor will monitor you for overgrowth and treat you if necessary.
- are pregnant or planning to become pregnant.
- have kidney problems.
- are breast-feeding or if you intend to breast-feed.
- are taking or have recently taken any other medicines, including medicines you get without a prescription.
- are under 18 years of age. ZEVTERA should not be given to children or adolescents as there is no experience with the use of ZEVTERA in children.
- have any allergies to any medicines, including antibiotics.
- are on a controlled sodium diet.
- have diarrhea during or after being given ZEVTERA.
- have a history of severe hypersensitivity reactions to antibiotics.
- have a history of seizures.
- are HIV positive.
- have a severely weakened immune system.
- have very low white blood counts.
- have a lowered bone marrow function.

Other warnings you should know about:

Driving and using machines: You may feel dizzy after receiving ZEVTERA. Therefore, it is not recommended to drive or use machines after receiving ZEVTERA.

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 ZEVTERA:

- statins (pitavastatin, pravastatin, rosuvastatin), glyburide, and bosentan

How to take ZEVTERA:

- ZEVTERA will be given to you by a doctor or nurse.

Usual adult dose:

The pharmacist or healthcare professional will prepare the product for use.

The recommended dose is 500 mg ceftobiprole every 8 hours given as a drip into a vein over a period of 2 hours. Treatment usually lasts 4-14 days for CAP and 7-14 days for HAP. Your doctor will decide on the duration of treatment. You may need a lower dose if you have kidney problems.

Overdose:

There is no information available on overdosing of ZEVTERA.

If you think you, or a person you are caring for, have taken too much ZEVTERA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you think you have missed a dose of ZEVTERA, discuss this with your healthcare professional as soon as possible.

What are possible side effects from using ZEVTERA?

These are not all the possible side effects you may have when taking ZEVTERA. If you experience any side effects not listed here, tell your healthcare professional.

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 ZEVTERA and contact your healthcare professional immediately.

The following side effects may happen with this medicine. The frequency category is based on reporting of the side effect, whether or not the side effect was caused by the drug.

Common: may affect between 1% and 10% of people

Headache, drowsiness (somnolence)

Feeling dizzy

Unusual taste (dysgeusia)

Rash, itching or hives - Contact your doctor if these symptoms persist

Feeling sick (nausea), being sick (vomiting) - Contact your doctor if these symptoms persist

Redness, pain or swelling were the injection was given - Contact your doctor if these symptoms persist

Uncommon: may affect between 0.1% and 1% of people

Stomach pain (abdominal pain), indigestion or “heartburn” (dyspepsia)

Muscle cramps

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**	
COMMON			
Sudden swelling of your lips, face, throat or tongue; a severe rash; and, swallowing or breathing problems. These may be signs of a severe allergic reaction (anaphylaxis) and may be life threatening.			✓
Hypersensitivity including skin reddening		✓	
Diarrhea. Tell your doctor straight away if you get diarrhea.		✓	
Diarrhea that becomes severe or does not go away or stool that contains blood or mucus during or after treatment with ZEVTERA. In this situation, you should not take medicines that stop or slow bowel movement.			✓
Low levels of the mineral 'sodium' in your blood		✓	
Increase in the level of some liver enzymes in your blood.		✓	
Fungal infections in different parts of your body	✓		
Convulsions, seizures, or fits			✓
UNCOMMON			
Temporarily decreased or increased numbers of certain types of blood cells		✓	
Shortness of breath or difficulty breathing, asthma			✓
Swelling, particularly of the ankles and legs		✓	
Kidney problems		✓	
Blood testing showing temporarily increased levels of triglycerides, blood sugar, or creatinine		✓	
Blood testing showing decreased levels of potassium		✓	

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**	
Sleeplessness and sleep disturbances, maybe including anxiety, panic attacks and nightmares	✓		
UNKNOWN			
Agranulocytosis (decrease in white blood cells): frequent infection with fever, chills, sore throat			✓
Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs): • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough • Shortness of breath, chest pain or discomfort			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) 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 of vials:

Keep out of reach and sight of children.

The healthcare professional will store the product under refrigeration (2°C - 8°C) in the carton to protect from light, before reconstitution.

If you want more information about ZEVTERA:

- 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: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.avirpharma.com), or by calling 1-888-430-0436.

This information is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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