



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Zerbaxa (*ceftolozane / tazobactam*)

An overview of Zerbaxa and why it is authorised in the EU

What is Zerbaxa and what is it used for?

Zerbaxa is an antibiotic used to treat adults and children with:

- complicated (difficult to treat) infections of tissues and organs within the belly (intra-abdominal infections);
- serious kidney infection (acute pyelonephritis);
- complicated infections of the urinary tract (structures that carry urine, such as the bladder).

It is also used to treat adults with hospital-acquired pneumonia (an infection of the lungs that is caught in the hospital), including ventilator-associated pneumonia (pneumonia in patients using a ventilator, a machine that helps a patient to breathe).

Zerbaxa contains the active substances ceftolozane and tazobactam.

How is Zerbaxa used?

Zerbaxa is available for infusion (drip) into a vein and can only be obtained with a prescription. It is given over 1 hour, every 8 hours. The dose and duration of treatment depend on the infection being treated and how the infection responds to the medicine. For children the dose and duration also depend on body weight. For more information about using Zerbaxa, see the package leaflet or contact your doctor or pharmacist.

How does Zerbaxa work?

The active substances in Zerbaxa, ceftolozane and tazobactam, work in different ways. Ceftolozane is a type of antibiotic called a cephalosporin, which belongs to the wider group of antibiotics called beta-lactams. It works by interfering with the production of molecules that bacteria need to build their protective cell walls. This causes weakness in the bacterial cell walls which then become prone to collapse, ultimately leading to the death of the bacteria.

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Tazobactam blocks the action of bacterial enzymes called beta-lactamases. These enzymes enable bacteria to break down beta-lactam antibiotics like ceftolozane, making the bacteria resistant to the antibiotic's action. By blocking the action of these enzymes, tazobactam allows ceftolozane to act against bacteria that would otherwise be resistant to this antibiotic .

What benefits of Zerbaxa have been shown in studies?

Zerbaxa has been shown to be at least as effective as other antibiotics in curing infections in three main studies.

One study involved 1,083 adults who mostly had kidney infection or in some cases a complicated urinary-tract infection. Zerbaxa successfully treated the infection in about 85% of the cases where it was given (288 of 340), compared with 75% (266 of 353) of those given another antibiotic called levofloxacin.

The second study involved 993 adults with complicated intra-abdominal infections. Zerbaxa was compared with another antibiotic, meropenem. Both medicines cured 94% of patients (353 out of 375 given Zerbaxa and 375 out of 399 given meropenem).

The third study involved 726 adults who were using a ventilator and who had either hospital-acquired pneumonia or ventilator-associated pneumonia. It found Zerbaxa to be at least as effective as meropenem: the infection had resolved in 54% of patients (197 out of 362) after 7 to 14 days of treatment with Zerbaxa compared with 53% of patients (194 out of 362) on meropenem. Three studies conducted in children younger than 18 years old showed that the way Zerbaxa is absorbed, modified and removed from the body in this age group and in adults is similar. Zerbaxa is therefore expected to show similar effectiveness.

What are the risks associated with Zerbaxa?

The most common side effects with Zerbaxa (which may affect up to 1 in 10 people) are nausea (feeling sick), headache, constipation, diarrhoea, fever and increased liver enzyme levels. Side effects in children are similar to those in adults, with the following additional common side effects (which may affect up to 1 in 10 children): low levels of neutrophils (a type of white blood cell), increased appetite, and dysgeusia (taste disturbance). There is little data on the side effects of Zerbaxa in children younger than 3 months of age with complicated intra-abdominal infections. For the full list of side effects of Zerbaxa, see the package leaflet.

Zerbaxa must not be used in people who are hypersensitive (allergic) to Zerbaxa or any of its ingredients, or in those who are hypersensitive to other cephalosporin antibiotics or have ever had a severe allergic reaction to another beta-lactam antibiotic.

Why is Zerbaxa authorised in the EU?

The European Medicines Agency decided that Zerbaxa's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that Zerbaxa was effective at curing infections in the patients studied, but acknowledged that only a limited number of patients with complicated urinary tract infections had been included. The Agency also noted that tazobactam is not active against some classes of beta-lactamase that can cause problems of resistance. Regarding safety, side effects were considered to be typical and expected for an antibiotic of this kind.

What measures are being taken to ensure the safe and effective use of Zerbaxa?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zerbaxa have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zerbaxa are continuously monitored. Side effects reported with Zerbaxa are carefully evaluated and any necessary action taken to protect patients.

Other information about Zerbaxa

Zerbaxa received a marketing authorisation valid throughout the EU on 18 September 2015.

Further information on Zerbaxa can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/zerbaxa.

This overview was last updated in 07-2022.