



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Exblifep (*cefepime / enmetazobactam*)

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

What is Exblifep and what is it used for?

Exblifep is an antibiotic used in adults to treat:

- complicated (difficult to treat) infections of the urinary tract (parts of the body that collect and pass out urine), including pyelonephritis (kidney infection);
- hospital-acquired pneumonia (an infection of the lungs that is caught at the hospital), including ventilator-associated pneumonia (pneumonia that develops in patients who use a machine called a ventilator to help them breathe);
- bacteraemia (bacteria in the blood) when it is associated or suspected to be associated with complicated urinary tract infection or hospital-acquired pneumonia.

Prescribers should consider official guidance on the appropriate use of antibiotics.

Exblifep contains two active substances, cefepime and enmetazobactam.

How is Exblifep used?

The medicine can only be obtained with a prescription.

Exblifep is given as an infusion (drip) into a vein. The infusion is given every 8 hours and lasts 2 hours (for complicated urinary tract infection, including pyelonephritis) or 4 hours (for hospital-acquired pneumonia, including ventilator-associated pneumonia).

The duration of treatment is 7 to 14 days depending on the severity and location of the infection and the response to treatment.

For more information about using Exblifep, see the package leaflet or contact your doctor or pharmacist.

How does Exblifep work?

The active substances in Exblifep, cefepime and enmetazobactam, work in different ways.

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Cefepime is a type of antibiotic called a cephalosporin, which belongs to the wider group of antibiotics called "beta-lactams". It works by preventing certain bacteria from making their own cell walls, thereby killing the bacteria.

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

What benefits of Exblifep have been shown in studies?

In a study involving 1041 adults, Exblifep was shown to be more effective than another antibiotic combining a beta-lactam and a beta-lactamase inhibitor (piperacillin and tazobactam) at treating complicated urinary tract infections, including acute pyelonephritis (sudden kidney infection). After 7 to 14 days, around 79% (273 out of 345) of patients treated with Exblifep had a favourable outcome (as measured by being cured of their symptoms and the absence of the bacteria that caused the infection in the blood) compared to around 59% (196 out of 333) of patients treated with piperacillin and tazobactam.

A study involving 19 healthy adults evaluated the distribution of Exblifep in the body. It showed that the medicine is able to penetrate the lungs sufficiently to support the use of Exblifep in the treatment of hospital-acquired pneumonia.

What are the risks associated with Exblifep?

For the full list of side effects and restrictions with Exblifep, see the package leaflet.

The most common side effects with Exblifep (which may affect up to 1 in 10 people) include high levels of alanine aminotransferase and aspartate aminotransferase (liver enzymes), as well as diarrhoea and phlebitis (inflammation of a vein) at the site of infusion. Serious side effects with Exblifep include colitis (inflammation of the colon) due to the bacteria *Clostridioides difficile* (which may affect more than 1 in 1,000 people).

Exblifep must not be used in people who are hypersensitive (allergic) to the cephalosprin group of antibiotics or who have severe hypersensitivity to other beta-lactam antibiotics.

Why is Exblifep authorised in the EU?

The European Medicines Agency decided that Exblifep's benefits are greater than its risks and it can be authorised for use in the EU.

At the time of approval of Exblifep, there was an unmet medical need for antibiotics that are safe and effective in treating infections caused by bacteria resistant to multiple authorised antibiotics. Studies show that Exblifep is effective in treating complicated urinary tract infections, including pyelonephritis, and hospital-acquired pneumonia, including ventilator-associated pneumonia, with or without bacteraemia. Therefore, Exblifep is an alternative treatment for these difficult-to-treat infections, especially those caused by bacteria producing certain types of beta-lactamases. The side effects of Exblifep are generally similar to those of other antibiotics of the same family and of cefepime when used alone. Overall, the safety profile of Exblifep was considered acceptable.

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

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

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

Other information about Exblifep

Exblifep received a marketing authorisation valid throughout the EU on 21 March 2024.

Further information on Exblifep can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/exblifep.

This overview was last updated in 03-2024.