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Emblaveo (*aztreonam / avibactam*)

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

What is Emblaveo and what is it used for?

Emblaveo is an antibiotic used in adults to treat:

- Complicated (difficult to treat) intra-abdominal (belly) infections;
- Hospital-acquired pneumonia (an infection of the lungs that is caught during a hospital stay), including ventilator-associated pneumonia (pneumonia that develops in patients who use a machine called a ventilator to help them breathe);
- Complicated infections of the urinary tract (parts of the body that collect and pass out urine), including pyelonephritis (kidney infection);
- Infections due to certain types of bacteria called aerobic gram-negative bacteria when patients have limited treatment options.

Emblaveo contains the active substances aztreonam and avibactam.

How is Emblaveo used?

The medicine can only be obtained with a prescription and prescribers should consider official guidance on the appropriate use of antibiotics. Treatment of infections with aerobic gram-negative bacteria should only be started after consultation with a doctor experienced in the management of infectious diseases.

Emblaveo is given as an infusion (drip) into a vein that lasts 3 hours. It is given every 6 to 12 hours, depending on how well the patient's kidneys work. The duration of treatment is 5 to 14 days, depending on the type of infection.

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

How does Emblaveo work?

The active substances in Emblaveo, aztreonam and avibactam, work in different ways. Aztreonam is a type of antibiotic called monobactam, 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 them.

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

What benefits of Emblaveo have been shown in studies?

Based on studies with Emblaveo, the medicine is expected to be effective at treating infections for which aztreonam is already used (complicated intra-abdominal and urinary infections, and hospital-acquired pneumonia), as well as other infections due to aerobic gram-negative bacteria.

Laboratory studies have shown that avibactam can protect aztreonam from being broken down by certain beta-lactamases, and that aztreonam and avibactam, the active substances in Emblaveo, can kill aerobic gram-negative bacteria.

The company provided existing data on the safety and effectiveness of aztreonam in its authorised uses. It also provided data on how avibactam behaves in the body when given in combination with ceftazidime (another beta-lactam antibiotic).

Two additional studies provided supportive data on Emblaveo.

In the first study, involving 422 adults with complicated intra-abdominal infection or hospital-acquired pneumonia caused by gram-negative bacteria, about 68% (193 out of 282) of patients treated with Emblaveo with or without the antibiotic metronidazole were cured of their infection, compared with about 66% (92 out of 140) of patients treated with another antibiotic treatment (meropenem with or without colistin).

In the second study, which involved 15 patients with complicated intra-abdominal or urinary infections, hospital-acquired pneumonia or bloodstream infection caused by gram-negative bacteria resistant to multiple antibiotics, about 42% (5 out of 12) of patients taking Emblaveo with or without metronidazole were cured of their infection, compared with none (out of 3) who were taking the best available treatment.

What are the risks associated with Emblaveo?

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

The most common side effects with Emblaveo (which may affect up to 1 in 10 people) include anaemia, diarrhoea and elevated blood levels of liver enzymes.

Why is Emblaveo authorised in the EU?

At the time of approval, there was an unmet medical need for antibiotics that are safe and effective in treating infections caused by bacteria resistant to multiple authorised antibiotics. Previous studies with aztreonam and avibactam, as well as additional laboratory and supportive studies with Emblaveo, show that the medicine Scan be expected to be effective in treating a range of serious infections, including infections caused by gram-negative bacteria, when patients have limited therapeutic options. Therefore, Emblaveo is an additional treatment option for these difficult-to-treat infections. The side effects of Emblaveo are generally similar to those of other antibiotics of the same family and of aztreonam when used alone. Overall, the safety profile of Emblaveo was considered acceptable.

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

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

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

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

Other information about Emblaveo

Emblaveo received a marketing authorisation valid throughout the EU on 22 April 2024.

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

This overview was last updated in 04-2024.