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Vabomere (*meropenem / vaborbactam*)

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

What is Vabomere and what is it used for?

Vabomere is an antibiotic used in adults to treat the following infections, including when they have spread into the blood (bacteraemia):

- complicated (difficult-to-treat) infections of the urinary tract, including kidneys;
- complicated abdominal infections of the tissues and organs in the belly (intra-abdominal infections);
- lung infections caught in hospital (hospital-acquired pneumonia), including ventilator-associated pneumonia (pneumonia caught from a ventilator, which is a machine that helps a patient to breathe).

It can also be used for infections caused by Gram-negative bacteria when other treatments might not work.

Vabomere contains the active substances meropenem and vaborbactam.

How is Vabomere used?

Vabomere can only be obtained with a prescription.

Vabomere is given by infusion (drip) into a vein over 3 hours. It is given every 8 hours and the duration of treatment depends on the type of infection and its severity.

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

How does Vabomere work?

The active substances in Vabomere, meropenem and vaborbactam, work in different ways. Meropenem belongs to the carbapenem class of antibiotics, which belongs to the wider group of antibiotics known as beta-lactams. It works by interfering with the activity of certain proteins that bacteria need to build

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their cell walls. This action weakens the bacterial cell walls which can then collapse, ultimately causing the bacteria to die. Meropenem has been authorised in the EU since the 1990s.

Vaborbactam is a beta-lactamase inhibitor, which means that it blocks the action of bacterial enzymes called beta-lactamases. These enzymes break down beta-lactam antibiotics such as meropenem and stop them from working. By blocking the action of these enzymes, vaborbactam allows meropenem to act against bacteria that would otherwise be resistant to it.

What benefits of Vabomere have been shown in studies?

Vabomere was found effective at treating infections in two studies. The first study, involving patients with complicated urinary tract infection (including kidney infection), compared Vabomere with a combination of piperacillin (another beta-lactam antibiotic) and tazobactam (a beta-lactamase inhibitor). Tests for bacteria in the urine found that 67% (128 out of 192) of patients treated with Vabomere were cured, compared with 58% (105 out of 182) of patients treated with piperacillin and tazobactam.

The second study involved patients with complicated urinary tract infection (including kidney infection), complicated intra-abdominal infections, lung infections caught in hospital and bacteraemia. Vabomere was compared with the doctor's choice of the best available antibiotic treatment. Of those treated with Vabomere, overall 60% (21 out of 35) of patients were cured, compared with 32% (6 out of 19) of patients receiving best available antibiotic treatment. Fewer patients treated with Vabomere (14%) died within 4 weeks compared with those receiving best available antibiotic treatment (26%).

What are the risks associated with Vabomere?

The most common side effects with Vabomere (which may affect up to 1 in 10 people) are headache, diarrhoea, inflammation of the vein around the infusion site and nausea (feeling sick). For the full list of side effects of Vabomere, see the package leaflet.

Vabomere must not be used in patients who are hypersensitive (allergic) to any carbapenem antibiotic or in patients who have had a severe allergic reaction to the broader class of beta-lactam antibiotics (such as penicillins and cephalosporins). For the full list of restrictions, see the package leaflet.

Why is Vabomere authorised in the EU?

The European Medicines Agency noted that there were limited options for treating infections with bacteria that carry beta-lactamases. Vaborbactam allows meropenem to work in many such infections by blocking certain beta-lactamases. However, the Agency recognised that Vabomere cannot deal with all types of bacteria resistant to meropenem. No special concerns about side effects have been raised by the addition of vaborbactam to meropenem. The Agency decided that Vabomere'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 Vabomere?

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

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

Other information about Vabomere

Vabomere received a marketing authorisation valid throughout the EU on 20 November 2018.

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

This overview was last updated in 11-2018.