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EPAR summary for the public

Vibativ telavancin

This is a summary of the European public assessment report (EPAR) for Vibativ. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Vibativ.

What is Vibativ?

Vibativ is a medicine that contains the active substance telavancin. It is available as a powder to be made up into a solution for infusion (drip) into a vein.

What is Vibativ used for?

Vibativ is used to treat adults with nosocomial pneumonia (an infection of the lungs). 'Nosocomial' means the infection was caught in hospital. This includes pneumonia caused by the use of a ventilator (a machine used in hospitals that helps patients to breathe). Vibativ is used only when the infection is known or believed to be caused by bacteria called 'methicillin-resistant *Staphylococcus aureus*' (MRSA) and when other treatments (such as other antibiotics) are not suitable.

The medicine can only be obtained with a prescription.

How is Vibativ used?

Vibativ is given as a drip into a vein lasting one hour. The recommended dose is 10 mg per kg body weight once every 24 hours, for seven to 21 days. For obese patients, a lower dose of 7.5 mg per kg body weight once every 24 hours is recommended. Kidney function should be monitored and the initial and subsequent doses may have to be lowered for patients with minor kidney problems, while treatment may need to be stopped if kidney function gets markedly worse. For further information see the summary of product characteristics (also part of the EPAR).



How does Vibativ work?

The active substance in Vibativ, telavancin, is an antibiotic that belongs to the group 'glycopeptides'. It works by stopping the bacteria causing the infection from making their own cell walls and by disrupting their cell membranes, thereby killing the bacteria. It is effective against MRSA bacteria, which are resistant to other commonly used groups of antibiotics such as penicillins (including methicillin and oxacillin) and cephalosporins.

How has Vibativ been studied?

Vibativ was compared with vancomycin (another antibiotic) in two main studies involving a total of 1,503 adults with nosocomial pneumonia caused by Gram-positive bacteria (types of bacteria that include MRSA). The antibiotics were given for up to 21 days. Vibativ was also compared with vancomycin in two main studies involving a total of 1,897 adults with complicated infections of the skin and soft tissue below the skin caused by Gram-positive bacteria, where the medicines were given for up to 14 days. In all the studies, the main measure of effectiveness was the number of patients whose infection had been cured after the end of treatment.

What benefit has Vibativ shown during the studies?

Vibativ was as effective as vancomycin at curing nosocomial pneumonia and complicated infections of the skin and soft tissue. In the first study in nosocomial pneumonia, 58% of patients treated with Vibativ (214 out of 372) were cured after treatment compared with 59% of patients treated with vancomycin (221 out of 374). In the second study, 60% of patients treated with Vibativ (227 out of 377) were cured after treatment compared with 60% of patients treated with vancomycin (228 out of 380).

In the first study in complicated infections of the skin and soft tissue, 76% of patients treated with Vibativ (323 out of 426) were cured after treatment compared with 75% treated with vancomycin (321 out of 429). In the second study, 77% of patients treated with Vibativ (387 out of 502) were cured after treatment compared with 74% of those treated with vancomycin (376 out of 510).

What is the risk associated with Vibativ?

The most common side effects with Vibativ (seen in more than 1 patient in 10) are dysgeusia (taste disturbances) and nausea (feeling sick). Studies showed that more patients developed kidney problems following treatment with Vibativ than with vancomycin (3.8% versus 2.2%). For the full list of all side effects reported with Vibativ, see the package leaflet.

Vibativ must not be given to patients with severe kidney problems or acute (sudden) kidney failure. In addition, care should be taken when giving Vibativ to patients taking other medicines that could cause kidney problems, those who already have kidney disease or have other diseases that make them more likely to have kidney problems, such as diabetes, congestive heart failure (a type of heart disease) and hypertension (high blood pressure). Vibativ must also not be given to pregnant women. For the full list of restrictions with Vibativ, see the package leaflet.

Why has Vibativ been approved?

The CHMP concluded that, although Vibativ had been shown to be effective in treating both nosocomial pneumonia and complicated infections of the skin and soft tissue, its toxic effect on the kidneys was an important safety concern. However, the Committee considered that Vibativ could be valuable for

treating patients with nosocomial pneumonia known or believed to be caused by MRSA for whom other treatments are not suitable. Therefore, the CHMP decided that Vibativ's benefits are only greater than its risks for patients who are severely ill with nosocomial pneumonia and are under close observation in hospital, and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Vibativ?

The company that markets Vibativ will ensure all doctors who are expected to prescribe or use Vibativ receive a letter and an educational pack containing the summary of product characteristics, package leaflet and a guide setting out important safety information on the correct use of Vibativ. The company will carry out a study to assess side effects that are experienced by patients using Vibativ and another to monitor for the development of bacteria resistant to the medicine. It will also maintain a registry of patients inadvertently treated with Vibativ during pregnancy, to monitor the subsequent effect on development of children from birth to 12 months of age.

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

Other information about Vibativ

The European Commission granted a marketing authorisation valid throughout the European Union for Vibativ on 2 September 2011.

The full EPAR for Vibativ can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with Vibativ, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2016.