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EPAR summary for the public

Orbactiv

oritavancin

This is a summary of the European public assessment report (EPAR) for Orbactiv. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Orbactiv.

For practical information about using Orbactiv, patients should read the package leaflet or contact their doctor or pharmacist.

What is Orbactiv and what is it used for?

Orbactiv is an antibiotic used in adults to treat acute (short-term) bacterial infections of the skin and of skin structures (tissue below the skin) such as cellulitis (inflammation of the deep skin tissue), skin abscesses and wound infections. It contains the active substance oritavancin.

Before using Orbactiv, doctors should consider official guidance on the appropriate use of antibiotics.

How is Orbactiv used?

Orbactiv is available as a powder to be made up into a solution for infusion (drip) into a vein and can only be obtained with a prescription. The recommended dose is a single infusion of 1,200 mg over three hours.

How does Orbactiv work?

The active substance in Orbactiv, oritavancin, is a type of antibiotic called a glycopeptide. It works by preventing certain bacteria from making their own cell walls, thereby killing the bacteria. Orbactiv has been shown to work against bacteria (such as methicillin resistant *Staphylococcus aureus* (MRSA)) for which standard antibiotics do not work. A list of bacteria against which Orbactiv is active can be found in the summary of product characteristics (also part of the EPAR).

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What benefits of Orbactiv have been shown in studies?

Orbactiv, given as a single infusion, was compared with a 7 to 10-day treatment with vancomycin (another glycopeptide) in two main studies involving a total of around 1,959 patients with acute bacterial infections of the skin and of skin structures, such as cellulitis, skin abscesses and wound infections. These also included infections caused by MRSA.

In both studies, the main measure of effectiveness was the number of patients who responded within 3 days of starting treatment with an improvement in their skin in the infected area, lack of fever and no need for additional antibiotic. The study also looked at the number of patients whose infection was cured after treatment.

Orbactiv was at least as effective as vancomycin at treating the infection: 80.1% of patients treated with Orbactiv in the first study and 82.3% in the second study responded to treatment, compared with 82.9% and 78.9% respectively of patients treated with vancomycin. In addition, 82.7% of patients treated with Orbactiv in the first study and 79.6% in the second study were cured, compared with 80.5% and 80.0% respectively of patients treated with vancomycin.

What are the risks associated with Orbactiv?

The most common side effects with Orbactiv (which may affect 5 people or more in 100) are nausea (feeling sick), hypersensitivity (allergy) reactions or reactions at the site of infusion and headache. The most common side effects that resulted in treatment being stopped were cellulitis and osteomyelitis (bone infection).

Patients who have received Orbactiv must not be given an infusion of unfractionated heparin (a medicine used to prevent blood clots) for 120 hours after the infusion of Orbactiv. For the full list of all side effects and restrictions with Orbactiv, see the package leaflet.

Why is Orbactiv approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Orbactiv's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that Orbactiv, which can be given as a single dose, could be a valuable alternative treatment option for acute bacterial infections of the skin and of skin structures. Although Orbactiv's safety profile overall is similar to that of other glycopeptides, the CHMP noted that some side effects occurred more frequently such as abscesses and bone infections. The CHMP considered that these side effects were manageable and adequately addressed in the product information.

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

A risk management plan has been developed to ensure that Orbactiv is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Orbactiv, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Orbactiv

The European Commission granted a marketing authorisation valid throughout the European Union for Orbactiv on 19 March 2015.

The full EPAR and risk management plan summary for Orbactiv 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 Orbactiv, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.