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Tenkasi[1] (*oritavancin*)

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

What is Tenkasi and what is it used for?

Tenkasi is an antibiotic used in adults and children from 3 months of age 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.

How is Tenkasi used?

Tenkasi is given as a single infusion (drip) into a vein. The medicine can only be obtained with a prescription. Before using Tenkasi, doctors should consider official guidance on the appropriate use of antibiotics.

For more information about using Tenkasi, see the package leaflet or contact your healthcare provider.

How does Tenkasi work?

The active substance in Tenkasi, 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. Tenkasi has been shown to work against bacteria (such as methicillin resistant *Staphylococcus aureus* (MRSA)) for which standard antibiotics do not work.

What benefits of Tenkasi have been shown in studies?

Tenkasi, 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

[1] Previously known as Orbactiv

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need for additional antibiotic. The study also looked at the number of patients whose infection was cured after treatment.

Tenkasi was at least as effective as vancomycin at treating the infection: 80.1% of patients treated with Tenkasi 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 Tenkasi 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.

An additional study involving 38 children from 3 months to less than 18 years of age showed that when given at the recommended dose in children of this age range, Tenkasi led to blood levels of the active substance, oritavancin, similar to those seen in adults.

What are the risks associated with Tenkasi?

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

The most common side effects with Tenkasi (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 Tenkasi must not be given an infusion of unfractionated heparin (a medicine used to prevent blood clots) for 120 hours after the infusion of Tenkasi. For the full list of side effects and restrictions with Tenkasi, see the package leaflet.

Why is Tenkasi authorised in the EU?

The European Medicines Agency noted that Tenkasi, 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. .

Tenkasi's safety profile overall is similar to that of other glycopeptides, although some side effects occurred more frequently such as abscesses and bone infections. EMA considered that these side effects were manageable and adequately addressed in the product information.

The European Medicines Agency concluded that Tenkasi'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 Tenkasi?

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

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

Other information about Tenkasi

Orbactiv received a marketing authorisation valid throughout the EU on 19 March 2015. The name of the medicine was changed to Tenkasi on 09 August 2021.

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

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