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**EPAR summary for the public**

*Sivextro*

tedizolid

This is a summary of the European public assessment report (EPAR) for Sivextro. 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 Sivextro.

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

**What is Sivextro and what is it used for?**

Sivextro 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 tedizolid.

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

**How is Sivextro used?**

Sivextro is available as a powder to be made up into a solution for infusion (drip) into a vein and as tablets (200 mg). The recommended dose is 200 mg once a day for 6 days. Patients who are started on the infusion may be switched to the tablets when appropriate.

Sivextro can only be obtained with a prescription.

**How does Sivextro work?**

The active substance in Sivextro, tedizolid, is a type of antibiotic called an oxazolidinone. It works by preventing certain bacteria from making proteins, thereby stopping their growth. Sivextro 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 Sivextro is active can be found in the summary of product characteristics (also part of the EPAR).
What benefits of Sivextro have been shown in studies?

Sivextro was compared with linezolid (another oxazolidinone) in two main studies involving a total of 1,333 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 patients received 6 days of treatment with Sivextro which was compared with a 10-day treatment of linezolid.

In both studies, the main measure of effectiveness was the number of patients whose infection was cured after treatment.

Sivextro was at least as effective as linezolid at curing the infection. 85.5% of patients treated with Sivextro in the first study and 88.0% in the second study were cured, compared with 86.0% and 87.7% respectively of patients treated with linezolid.

What are the risks associated with Sivextro?

The most common side effects with Sivextro (which may affect between 2 and 7 people in 100) are nausea (feeling sick), headache, diarrhoea and vomiting. These side effects were generally of mild or moderate severity.

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

Why is Sivextro approved?

The Agency’s Committee for Medicinal Products for Human Use (CHMP) decided that Sivextro’s benefits are greater than its risks and recommended that it be approved for use in the EU. Although the infections in the studies were not severe, the CHMP considered that the results also apply to severe infections. In light of the need for new antibiotics targeting multi-resistant bacteria, especially those available as an oral (given by mouth) formulation, the CHMP concluded that Sivextro could be a valuable alternative treatment option for bacterial infections of the skin and of skin structures. Sivextro’s safety profile is comparable to that of linezolid and was considered acceptable.

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

A risk management plan has been developed to ensure that Sivextro 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 Sivextro, 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 Sivextro

The European Commission granted a marketing authorisation valid throughout the European Union for Sivextro on 23 March 2015.

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

This summary was last updated in 03-2015.