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Sivextro (*tedizolid*)

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

What is Sivextro and what is it used for?

Sivextro is an antibiotic used in patients from 12 years of age to treat acute (short-term) bacterial infections of the skin and of skin structures (tissue below the skin) such as cellulitis (infection of the skin and the tissue underneath), skin abscesses (a swollen area on the skin where pus has collected) and wound infections.

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

Sivextro contains the active substance tedizolid.

How is Sivextro used?

Sivextro is available for infusion (drip) into a vein and as tablets to take by mouth. 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.

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

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 meticillin-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.

What benefits of Sivextro have been shown in studies?

Sivextro was at least as effective as linezolid (another oxazolidinone antibiotic) in two main studies involving a total of 1,333 adults with acute bacterial infections of the skin and of skin structures, such as cellulitis, skin abscesses and wound infections. These included infections caused by MRSA. Of the

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patients treated with Sivextro, 85.5% were cured in the first study and 88.0% in the second study, compared with 86.0% and 87.7% respectively of patients treated with linezolid.

In a study involving 120 patients aged from 12 years up to 18 years, Sivextro was at least as effective as other medicines used for treating acute bacterial infections of the skin and of skin structures. The study also found that blood levels of the medicine in these patients were similar to those in adults treated with Sivextro.

What are the risks associated with Sivextro?

The most common side effects with Sivextro (which may affect up to 1 in 10 people) are headache, nausea (feeling sick), vomiting and diarrhoea.

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

Why is Sivextro authorised in the EU?

The European Medicines Agency decided that Sivextro's benefits are greater than its risks and it can be authorised for use in the EU.

Although the infections in the studies were not severe, the Agency considered that the results also apply to severe infections. Because of the need for new antibiotics against bacteria that have become resistant to several antibiotics, especially those that can be given by mouth, the Agency considered Sivextro a valuable treatment option for bacterial infections of the skin and of skin structures. Sivextro's pattern of side effects is comparable to that of linezolid and was considered acceptable.

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

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

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

Other information about Sivextro

Sivextro received a marketing authorisation valid throughout the EU on 23 March 2015.

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

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