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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 adults, adolescents and children to treat acute (short-term) bacterial infections of the skin and 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.

Sivextro contains the active substance tedizolid.

How is Sivextro used?

Sivextro can only be obtained with a prescription, and prescribers should consider official guidance on the appropriate use of antibiotics.

Sivextro is given as an infusion (drip) into a vein; for adults, adolescents and children weighing at least 35 kg, it is also available as tablets to be taken by mouth. Adults, adolescents and children weighing at least 35 kg who are started on the infusion may be switched to the tablets when appropriate. The duration of treatment is 6 days.

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 mainly against bacteria called Gram-positive bacteria, including those for which standard antibiotics do not work, such as methicillin-resistant *Staphylococcus aureus* (MRSA).

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 skin structures. These included infections caused by MRSA. The infection was cured in 85.5% of the patients treated with

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Sivextro in the first study and 88.0% in the second study, compared with 86.0% and 87.7%, respectively, of those treated with linezolid.

Two studies involving a total of 220 children and adolescents up to 18 years of age found that blood levels of Sivextro in these patients were similar to those seen in adults treated with the medicine. This is supported by data indicating that the effectiveness of Sivextro was comparable to that of other medicines in the treatment of acute bacterial infections of the skin and skin structures.

What are the risks associated with Sivextro?

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

In adults, the most common side effects with Sivextro (which may affect up to 1 in 10 people) include headache, nausea (feeling sick), vomiting and diarrhoea. In children, the most common side effects (which may affect up to 1 in 10 children) include nausea, vomiting and phlebitis (inflammation of a vein).

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 involving adults 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 skin structures. Based on data from studies in children from birth to 18 years old, the medicine is also expected to be effective in treating such infections in children and adolescents. 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.

This overview was last updated in 02-2025.