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Xydalba (*dalbavancin*)

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

What is Xydalba and what is it used for?

Xydalba is an antibiotic used in adults and children aged 3 months and older 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 dalbavancin.

How is Xydalba used?

Xydalba is given by infusion (drip) into a vein over 30 minutes. The recommended dose for adults is 1,500 mg, given either as a single infusion or as 1,000 mg in the first week followed by 500 mg one week later. For children, the dose depends on age and body weight and should not be more than 1,500 mg.

Xydalba can only be obtained with a prescription and prescribers should take into account official guidance on the use of antibiotics.

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

How does Xydalba work?

The active substance in Xydalba, dalbavancin, is a type of antibiotic called a glycopeptide. It works by preventing certain bacteria from making their own cell walls, thereby killing the bacteria. Dalbavancin 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 Xydalba is active can be found in the summary of product characteristics.

What benefits of Xydalba have been shown in studies?

Xydalba was compared with vancomycin (another glycopeptide) or with linezolid (another type of antibiotic, which can be taken by mouth) in three main studies involving a total of around 2,000 adults with serious infections of the skin and soft tissue under the skin, such as cellulitis, skin abscesses and wound infections. These also included infections caused by MRSA.

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Patients who received vancomycin and responded to treatment had the option to switch to linezolid after 3 days. In all the studies, the main measure of effectiveness was the number of patients whose infection was cured after treatment.

Xydalba was at least as effective as vancomycin or linezolid at curing the infection. In the 3 studies, between 87% and 94% of patients treated with Xydalba were cured, compared with between 91% and 93% of patients treated with any of the two comparators.

An ongoing study involving 198 children with serious infections of the skin and soft tissue under the skin found that Xydalba, given as a single dose or as two doses one week apart, resulted in levels of the active substance in the body similar to those seen in adults. Therefore, Xydalba is expected to have a comparable effect in children as in adults.

What are the risks associated with Xydalba?

The most common side effects with Xydalba (which may affect between 1 and 3 people in 100) are nausea (feeling sick), diarrhoea and headache. These side effects were generally of mild or moderate severity.

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

Why is Xydalba authorised in the EU?

The European Medicines Agency decided that Xydalba's benefits are greater than its risks and it can be authorised for use in the EU. In light of the need for new antibiotics targeting multi-resistant bacteria, the Agency concluded that Xydalba, which showed activity in adults against certain bacteria resistant to other antibiotics, could be a valuable alternative treatment option. The Agency also considered that the effect and safety profile of Xydalba in children are expected to be comparable to those seen in adults.

Xydalba's safety profile is comparable to that of other glycopeptide antibiotics; side effects affecting hearing and kidney function, which are typical for glycopeptides, have not been shown with the proposed regimens of Xydalba in the clinical trials.

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

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

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

Other information about Xydalba

Xydalba received a marketing authorisation valid throughout the EU on 19 February 2015.

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

This overview was last updated in 12-2022.