

EMA/225270/2016
EMA/H/C/002840

EPAR summary for the public

Xydalba

dalbavancin

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

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

What is Xydalba and what is it used for?

Xydalba 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 dalbavancin.

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

How is Xydalba used?

Xydalba is available as a powder to be made up into a solution for infusion (drip) into a vein and can only be obtained with a prescription. Xydalba is given once a week by an infusion lasting 30 minutes. The recommended dose 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. The dose of Xydalba needs to be reduced in patients with severely impaired kidney function.

How does Xydalba work?

The active substance in Xydalba, dalbavancin, is a type of antibiotic called 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 (also part of the EPAR).

What benefits of Xydalba have been shown in studies?

Xydalba was compared with vancomycin (another glycopeptide) or with linezolid (an antibiotic that can be taken by mouth) in three main studies involving a total of around 2,000 patients 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.

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.

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 approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Xydalba's benefits are greater than its risks and recommended that it be approved for use in the EU. In light of the need for new antibiotics targeting multi-resistant bacteria, the CHMP concluded that Xydalba, which showed activity against certain bacteria resistant to other antibiotics, could be a valuable alternative treatment option. Xydalba's safety profile is comparable to that of other antibiotics of the glycopeptide class; 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?

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

The European Commission granted a marketing authorisation valid throughout the European Union for Xydalba on 19 February 2015.

The full EPAR and risk management plan summary for Xydalba can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more

information about treatment with Xydalba, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2016.