LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dalbavancin Bioglan (dalbavancin)

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Summary Public Assessment Report

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dalbavancin

Powder for concentrate for solution for infusion, 500 mg.

This is a summary of the public assessment report (PAR) for Dalbavancin Bioglan. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Dalbavancin Bioglan and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Xydalba.

Dalbavancin Bioglan is used to treat adults and children aged 3 months and over with infections of the skin or in the layers of flesh below the skin.

How does Dalbavancin Bioglan work?
Dalbavancin Bioglan contains the active substance dalbavancin, which is an antibiotic of the glycopeptide group.

Dalbavancin Bioglan works by killing certain bacteria, which can cause serious infections. It kills these bacteria by interfering with the formation of bacterial cell walls.

Dalbavancin Bioglan can be used in combination with other types of antibiotics, if necessary.

How is Dalbavancin Bioglan used?
The pharmaceutical form is Powder for concentrate for solution for infusion for intravenous use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Dalbavancin Bioglan have been shown in studies?
No additional studies were needed as the product is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Xydalba.

What are the possible side effects from Dalbavancin Bioglan?
Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Dalbavancin Bioglan approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Xydalba, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Dalbavancin Bioglan?
A risk management plan has been developed to ensure that the product 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, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Dalbavancin Bioglan

The full PAR for Dalbavancin Bioglan can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Dalbavancin Bioglan, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-08.