LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Xelltempra
(daptomycin)

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Summary Public Assessment Report

Xelltempra
daptomycin

Powder for solution for injection/infusion, 350 mg, 500 mg

This is a summary of the public assessment report (PAR) for Xelltempra. 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 Xelltempra 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 Cubicin.

Xelltempra is used in adults and in children and adolescents (age from 1 to 17 years) to treat infections of the skin and the tissues below the skin. It is also used to treat infections in the blood when associated with skin infection.

Xelltempra is also used in adults to treat infections in the tissues that line the inside of the heart (including heart valves) which are caused by a type of bacteria called *Staphylococcus aureus*. It is also used to treat infections in the blood caused by the same type of bacteria when associated with heart infection.

Depending on the type of infection(s), the doctor may also prescribe other antibacterials while the patient is receiving treatment with Xelltempra.

How does Xelltempra work?

The active substance in Xelltempra powder for solution for injection/infusion is daptomycin. Daptomycin is an antibacterial that can stop the growth of certain bacteria.

How is Xelltempra used?

The pharmaceutical form is powder for solution for injection/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 Xelltempra have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Cubicin.

What are the possible side effects from Xelltempra?

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 Xelltempra approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Cubicin, 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 Xelltempra?

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 Xelltempra

The full PAR for Xelltempra can be found on the following website: MRI - Home. For more information about treatment with Xelltempra, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-10.