COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Daptomycine Lorien 350 mg and 500 mg, powder for solution for injection or infusion

(daptomycin)

NL/H/4241/001-004/DC

Date: 27 August 2019

Summary Public Assessment Report

Generics

Daptomycine Lorien 350 mg and 500 mg, powder for solution for injection or infusion

Active substance: daptomycin

This is a summary of the public assessment report (PAR) for Daptomycine Lorien. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Daptomycine Lorien.

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

What is Daptomycine Lorien and what is it used for?
Daptomycine Lorien is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Cubicin.

This medicine 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.

Daptomycine Lorien 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 receiving treatment with this medicine.

How does this medicine work?
The active substance in Daptomycine Lorien is daptomycin. Daptomycin is an antibacterial that can stop the growth of certain bacteria.

How is this medicine used?
The pharmaceutical form of Daptomycine Lorien is a powder for solution and can be administered by injection or infusion.

The medicine can only be obtained with a prescription.

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

How has this medicine been studied?
No additional studies were needed as Daptomycine Lorien is a generic medicine that is given by infusion or intravenous injection and contains the same active substance as the reference medicine, Cubicin.

What are the possible side effects of this medicine?
Because Daptomycine Lorien is a generic medicine and is identical to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be identical to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Cubicin, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Daptomycine Lorien, 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 this medicine
In the Netherlands, the marketing authorisation for Daptomycine Lorien was granted on 27 June 2019.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Daptomycine Lorien, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4241_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in August 2019.