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EPAR summary for the public

Daptomycin Hospira

daptomycin

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

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

What is Daptomycin Hospira and what is it used for?

Daptomycin Hospira is an antibiotic medicine used to treat the following bacterial infections:

- complicated infections of the skin and the 'soft tissues' below the skin in adults and children from 1 to 17 years of age. 'Complicated' means that the infection is difficult to treat, because it has spread to the deep tissues below the skin, because treatment with surgery might be needed, or because the patient has other conditions that might affect the treatment;
- right-sided infective endocarditis (infection of the lining or the valves of the right side of the heart) caused by the bacterium *Staphylococcus aureus* (*S. aureus*) in adults. The decision to treat this infection with Daptomycin Hospira should be based on the likelihood that the medicine will work against the infection and on advice from an expert;
- bacteraemia (infection of the blood) caused by *S. aureus*, associated with either of the two infections above, in adults.

Daptomycin Hospira contains the active substance daptomycin.

Daptomycin Hospira is a 'generic medicine'. This means that Daptomycin Hospira contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Cubicin. For more information on generic medicines, see the question-and-answer document here.

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How is Daptomycin Hospira used?

Daptomycin Hospira is available as a powder that is made up into a solution for injection or infusion (drip) into a vein. In adults, Daptomycin Hospira is given by a doctor or a nurse either as an infusion lasting 30 minutes or as an injection lasting two minutes. For skin or soft tissue infections without bacteraemia, Daptomycin Hospira is given at a dose of 4 mg per kilogram body weight once every 24 hours for 7 to 14 days or until the infection has cleared up. For endocarditis and for skin or soft tissue infection with bacteraemia, the dose is 6 mg/kg once every 24 hours.

In children aged 7 to 17 years with complicated skin or soft tissue infections, Daptomycin Hospira is given as an infusion lasting 30 minutes and in children aged 1 to 6 years the infusion should last 60 minutes. The dose changes with the child's age and varies between 5 to 10 mg/kg once every 24 hours for up to 14 days.

The duration of treatment depends on the risk of complications and official recommendations. Depending on the infection being treated and whether a patient has more than one infection, other antibiotics may be given during treatment with Daptomycin Hospira.

The medicine can only be obtained with a prescription. For more information, see the package leaflet.

How does Daptomycin Hospira work?

The active substance in Daptomycin Hospira, daptomycin, is an antibiotic that belongs to the group 'lipopeptides'. It can stop the growth of certain types of bacteria by attaching to the membrane around each bacterial cell and upsetting the essential functions that keep the cell alive. A list of bacteria against which Daptomycin Hospira is active can be found in the summary of product characteristics (also part of the EPAR).

How has Daptomycin Hospira been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Cubicin, and do not need to be repeated for Daptomycin Hospira.

As for every medicine, the company provided studies on the quality of Daptomycin Hospira. There was no need for 'bioequivalence' studies to investigate whether Daptomycin Hospira is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Daptomycin Hospira is given into a vein either by infusion or by injection, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Daptomycin Hospira?

Because Daptomycin Hospira is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Daptomycin Hospira approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Daptomycin Hospira has been shown to be comparable to Cubicin. Therefore, the CHMP's view was that, as for Cubicin, the benefit outweighs the identified risk. The Committee recommended that Daptomycin Hospira be approved for use in the EU.

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

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

Other information about Daptomycin Hospira

The European Commission granted a marketing authorisation valid throughout the European Union for Daptomycin Hospira on 22 March 2017.

The full EPAR for Daptomycin Hospira can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Daptomycin Hospira, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 02-2017.