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Daptomycin Hospira (*daptomycin*)

An overview of Daptomycin Hospira and why it is authorised in the EU

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 'soft tissue' below the skin in patients from 1 year of age. 'Complicated' means that the infection is difficult to treat, because it has spread to the deep tissues below the skin, treatment with surgery might be needed, or the patient has other conditions that might affect how well treatment works;
- 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.* It is used in adults, when the bacteraemia is associated with either of the two infections above, or in adolescents and children from 1 year of age when the bacteraemia is associated with complicated infections of the skin and soft tissue.

Prescribers should consider the official guidance on the use of antibiotics.

Daptomycin Hospira contains the active substance daptomycin. It 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.

How is Daptomycin Hospira used?

Daptomycin Hospira is given by infusion (drip) into a vein.

In adults, for skin or soft tissue infections without bacteraemia, Daptomycin Hospira is given at a dose of 4 mg/kg body weight once a day. For endocarditis and for skin or soft tissue infection with bacteraemia, the dose is 6 mg/kg once a day. Daptomycin Hospira is given into a vein as an infusion lasting 30 minutes or as an injection lasting 2 minutes.

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In children, the dose of Daptomycin Hospira for skin or soft tissue infection without bacteraemia depends on the child's age and ranges between 5 and 10 mg/kg body weight once a day. Higher doses (between 7 and 12 mg/kg once a day) are used if the skin or soft tissue infection is associated with bacteraemia. Daptomycin Hospira is given by infusion lasting 60 minutes in children aged 1 to 6 years and 30 minutes in those aged above 7 years.

The duration of treatment with Daptomycin Hospira depends on the risk of complications and official recommendations.

The medicine can only be obtained with a prescription. For more information about using Daptomycin Hospira, see the package leaflet or contact your doctor or pharmacist.

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 surrounding the bacterial cell and upsetting the essential functions that keep the cell alive.

How has Daptomycin Hospira been studied?

Studies on the benefits and risks of the active substance in the authorised 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, 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 authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Daptomycin Hospira has been shown to be comparable to Cubicin. Therefore, the Agency's view was that, as for Cubicin, the benefit of Daptomycin Hospira outweighs the identified risk and it can be authorised for use in the EU.

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

The company that markets Daptomycin Hospira will provide all doctors who are expected to use this medicine with a dosage card to ensure the safe use of Daptomycin Hospira. In addition, the company will also provide a leaflet for laboratories explaining how to test to see if an infection is likely to respond to the medicine.

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

As for all medicines, data on the use of Daptomycin Hospira are continuously monitored. Side effects reported with Daptomycin Hospira are carefully evaluated and any necessary action taken to protect patients.

Other information about Daptomycin Hospira

Daptomycin Hospira received a marketing authorisation valid throughout the EU on 22 March 2017.

Further information on Daptomycin Hospira can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/daptomycin-hospira

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 10-2019.