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Cubicin (*daptomycin*)

An overview of Cubicin and why it is authorised in the EU

What is Cubicin and what is it used for?

Cubicin is an antibiotic medicine, which is 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 type of infection with Cubicin 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 official guidance on the use of antibiotics.

Cubicin contains the active substance daptomycin.

How is Cubicin used?

Cubicin is available as a powder that is made up into a solution for injection or infusion (drip) into a vein.

In adults, for skin or soft tissue infections without bacteraemia, Cubicin 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. Cubicin is given into a vein as an infusion lasting 30 minutes or as an injection lasting 2 minutes.

In children the dose of Cubicin for skin or soft tissue infection without bacteraemia depends on the child's age and ranges between 5 and 10 mg/kg 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. Cubicin is given by infusion lasting 60 minutes in children aged 1 to 6 years and 30 minutes in those aged above 7 years.

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The duration of treatment with Cubicin depends on the risk of complications and official recommendations. The medicine can only be obtained with a prescription.

For more information about using Cubicin, see the package leaflet or contact your doctor or pharmacist.

How does Cubicin work?

The active substance in Cubicin, 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.

What benefits of Cubicin have been shown in studies?

Three main studies in adults and two in children aged between 1 and 17 years found that Cubicin was as effective as standard treatments at curing or improving infection. Standard treatments comprised use of antibiotics such as vancomycin, a penicillin (including oxacillin, cloxacillin, flucloxacillin and nafcillin) or a cephalosporin.

In the first two studies involving 1,118 adults with complicated skin and soft tissue infections (mainly wound infections and major abscesses), Cubicin was effective in 67% of patients in one study and in 85% in the other. Effectiveness varied between the two studies because of differences in the types of patients and infections being treated.

The third study involved 246 adults with bacteraemia caused by *S. aureus*, including 35 who also had right-sided infective endocarditis. In the group with endocarditis, treatment was successful in 42% (8 out of 19) of the patients receiving Cubicin compared with 44% (7 out of 16) of the patients receiving standard treatment. There was insufficient evidence to support the use of Cubicin to treat bacteraemia in patients who did not have either right-sided infective endocarditis or complicated skin and soft-tissue infections.

The first study in children and adolescents involved 396 patients with complicated skin and soft tissue infections without bacteraemia. Treatment was successful in 88% (227 out of 257) of the patients receiving Cubicin compared with 86% (114 out of 132) receiving standard treatment.

The second study in children and adolescents involved 73 patients with bacteraemia caused by *S. aureus*. Treatment was successful in 88% (45 out of 51) of the patients receiving Cubicin compared with 77% (17 out of 22) receiving standard treatment.

What are the risks associated with Cubicin?

The most common side effects with Cubicin (which may affect between 1 and 10 patients in 100) are infections caused by fungi (moulds and yeasts), urinary tract infections (infection of the structures that carry urine), *Candida* infection (a fungal infection), anaemia (low red blood cell counts), anxiety, insomnia (difficulty sleeping), dizziness, headache, hypertension (high blood pressure), hypotension (low blood pressure), gastrointestinal and abdominal pain (belly ache), nausea (feeling sick), vomiting, constipation, diarrhoea, flatulence (gas), bloating and distension (feeling as if the tummy is full), rash, pruritus (itching), pain in the limbs (arms or legs), infusion site reactions, pyrexia (fever), asthenia (weakness), abnormal liver tests and raised levels in the blood of an enzyme called CPK (a marker of muscle damage).

Serious side effects include hypersensitivity (allergic) reactions, eosinophilic pneumonia (infection of the lungs), drug rash with eosinophilia and systemic symptoms (DRESS, a severe reaction affecting the

skin, blood and internal organs), angioedema (rapid swelling of deeper skin tissues) and rhabdomyolysis (breakdown of muscle fibres).

For the full list of side effects and restrictions of Cubicin, see the package leaflet.

Why is Cubicin authorised in the EU?

Three main studies in adults and two in children showed that Cubicin was effective at treating infections. The side effects are considered manageable. The European Medicines Agency therefore decided that Cubicin's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

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

Other information about Cubicin

Cubicin received a marketing authorisation valid throughout the EU on 19 January 2006.

Further information on Cubicin can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/cubicin

This overview was last updated in 11-2022.