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EPAR summary for the public

Tygacil

tigecycline

This document is a summary of the European Public Assessment Report (EPAR) for Tygacil. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Tygacil.

What is Tygacil?

Tygacil is a powder that is made up into a solution for infusion (drip into a vein). It contains the active substance tigecycline.

What is Tygacil used for?

Tygacil is used to treat adults and children older than eight years with complicated infections of the skin and soft tissue (the tissue below the skin), but not foot infections in people with diabetes. It is also used to treat complicated infections in the abdomen. 'Complicated' means that the infection is difficult to treat. Tygacil should be used only when other antibiotics are not suitable. Before using Tygacil, doctors should consider official guidance on the appropriate use of antibiotics.

The medicine can only be obtained with a prescription.

How is Tygacil used?

In adults, the recommended dose of Tygacil is a starting dose of 100 mg, followed by 50 mg every 12 hours for five to 14 days. Each infusion should last between 30 and 60 minutes. The length of treatment depends on where the infection is, how severe it is, and the patient's response to treatment. Doses are lower in patients with severe liver problems.

In children above eight years of age, treatment is only given after consulting with a doctor with appropriate experience in the management of infectious diseases, and should be given as an infusion over a period of 60 minutes. In children from 8 to 12 years old a dose of 1.2 mg per kilogram body

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weight is given by infusion into a vein every twelve hours, up to a maximum dose of 50 mg every 12 hours. Treatment lasts from 5 to 14 days. In children from 12 to 18 years a dose of 50 mg is given every 12 hours for a period of 5 to 14 days.

How does Tygacil work?

The active substance in Tygacil, tigecycline, belongs to a group of antibiotics called 'glycylcyclines'. It works by blocking the bacteria's ribosomes, the parts of the cell where new proteins are made. By blocking the production of new proteins, the bacteria cannot multiply and they eventually die. The list of bacteria against which Tygacil is active can be found in the summary of product characteristics (also part of the EPAR).

How has Tygacil been studied?

Tygacil has been compared with other antibiotics in four main studies. In two of these studies, Tygacil was compared with the combination of vancomycin and aztreonam in 1,129 patients with complicated skin and soft tissue infections (not including infected diabetic foot ulcers). In the other two studies, Tygacil was compared with imipenem/cilastatin (a combination of two medicines used together as an antibiotic) in 1,568 patients with complicated infections in the abdomen. An additional study compared Tygacil with the antibiotic ertapenem in 813 diabetic patients with moderate to severe foot infections.

In all of the studies, the main measure of effectiveness was the number of patients whose infection was cured.

What benefit has Tygacil shown during the studies?

In the four main studies, Tygacil was as effective as the comparator antibiotics. In the studies of skin and soft tissue infections, around 86% of the patients receiving Tygacil were cured, compared with around 89% of those receiving vancomycin and aztreonam. In the studies of abdominal infection, around 86% of the patients receiving either Tygacil or imipenem/cilastatin were cured.

In the study looking at diabetic foot infections, Tygacil was less effective than ertapenem: 78% of the patients receiving Tygacil were cured, compared with 83% of those receiving ertapenem.

Although there are few data in children, studies suggest that Tygacil can be a treatment alternative for complicated skin and soft tissue or abdominal infections, with bacteria resistant to other antibiotics.

What is the risk associated with Tygacil?

The most common side effects with Tygacil are mild to moderate nausea (feeling sick) and vomiting, seen in 20% and 14% of patients, respectively. For the full list of all side effects reported with Tygacil, see the package leaflet.

Tygacil must not be used in people who are hypersensitive (allergic) to tigecycline or any of the other ingredients. Patients allergic to tetracycline antibiotics may also be allergic to Tygacil.

Why has Tygacil been approved?

The CHMP decided that Tygacil'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 Tygacil?

A risk management plan has been developed to ensure that Tygacil is used as safely and effectively as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tygacil, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Tygacil:

The European Commission granted a marketing authorisation valid throughout the European Union for Tygacil on 24 April 2006.

The full EPAR for Tygacil 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 Tygacil, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2015.