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# Tigecycline Accord (*tigecycline*)

An overview of Tigecycline Accord and why it is authorised in the EU

## What is Tigecycline Accord and what is it used for?

Tigecycline Accord is a medicine 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 because it has spread, or the patient has other conditions that makes treatment difficult. Tigecycline Accord should be used only when other antibiotics are not suitable. Before using Tigecycline Accord, doctors should consider official guidance on the appropriate use of antibiotics.

Tigecycline Accord is a 'generic medicine'. This means that Tigecycline Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Tygacil. For more information on generic medicines, see the question-and-answer document here.

Tigecycline Accord contains the active substance tigecycline.

## How is Tigecycline Accord used?

Tigecycline Accord is available as a powder that is made up into a solution for infusion (drip) into a vein. In adults, the recommended dose of Tigecycline Accord 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 weight is given by infusion into a vein every 12 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.

The medicine can only be obtained with a prescription.

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

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## How does Tigecycline Accord work?

The active substance in Tigecycline Accord, 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.

## How has Tigecycline Accord 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, Tygacil, and do not need to be repeated for Tigecycline Accord.

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

## What are the benefits and risks of Tigecycline Accord?

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

## Why is Tigecycline Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Tigecycline Accord has been shown to be comparable to Tygacil. Therefore, the Agency's view was that, as for Tygacil, the benefits of Tigecycline Accord outweigh the identified risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Tigecycline Accord?

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

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

## Other information about Tigecycline Accord

Tigecycline Accord received a marketing authorisation valid throughout the EU on 17 April 2020.

Further information on Tigecycline Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tigecycline-accord. Information on the reference medicine can also be found on the Agency's website.

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