EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2020
EMA/CHMP/73022/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tigecycline Accord

tigecycline

On 27 February 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tigecycline Accord, intended for the treatment of complicated skin and soft tissue infections (cSSTI) and complicated intra-abdominal infections (cIAI). The applicant for this medicinal product is Accord Healthcare S.L.U.

Tigecycline Accord will be available as a 50 mg powder for solution for infusion. The active substance of Tigecycline Accord is tigecycline, an antibacterial for systemic use (ATC code: J01AA12) which prevents bacterial growth by inhibiting protein synthesis.

Tigecycline Accord is a generic of Tygacil, which has been authorised in the EU since 24 April 2006. Studies have demonstrated the satisfactory quality of Tigecycline Accord. Since Tigecycline Accord is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Tygacil was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> "Tigecycline Accord is indicated in adults and in children from the age of eight years for the treatment of the following infections:
>
> - Complicated skin and soft tissue infections (cSSTI), excluding diabetic foot infections;
> - Complicated intra-abdominal infections (cIAI).
>
> Tigecycline Accord should be used only in situations where other alternative antibiotics are not suitable."

It is proposed that Tigecycline Accord be prescribed by physicians experienced in the management of infectious diseases.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.