



23 April 2015
EMA/CHMP/262234/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tygacil tigecycline

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Tygacil. The marketing authorisation holder for this medicinal product is Pfizer Limited.

The CHMP adopted a change to an existing indication as follows²:

“Tygacil is indicated in adults **and in children from the age of eight years** for the treatment of the following infections (see sections 4.4 and 5.1):

- Complicated skin and soft tissue infections (**cSSTI**), excluding diabetic foot infections (see section 4.4)
- Complicated intra-abdominal infections (**cIAI**)

Tygacil should be used only in situations where ~~it is known or suspected that~~ other alternatives **antibiotics** are not suitable (see sections 4.4, ~~and 4.8~~ **and 5.1**).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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

² **New text in bold, removed text as strikethrough**

