



EMA/329446/2015 Rev. 1

Update of 6 November 2019:

The shortage affecting Tygacil has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

22 May 2015

**Tygacil (tigecycline)
Powder for solution for infusion**

Indication	Tygacil is used to treat adults with complicated infections of the skin and soft tissue (the tissue below the skin).
Reason for shortage	In March 2015, during routine quality checks, particles were observed in the vial stoppers of some batches of Tygacil. The affected batches were not released, and manufacturing activity was temporarily suspended causing a temporary shortage of the medicine. As the particles are embedded in the stopper and not expected to become dislodged in routine handling there is no impact on product quality. The company is currently taking corrective and preventive measures and distribution is expected to resume beginning June 2015. Markets that entered shortage will be resupplied first.
Member States affected	Most EU member States where Tygacil is marketed (Austria, Belgium, Czech Republic, France, Germany, Greece, Italy, the Netherlands, Poland, Portugal, Romania, Spain and the United Kingdom).
Information to healthcare professionals	While Tygacil is unavailable doctors should use an alternative treatment. Additional advice may be available from the national competent authority .
Information to patients	Tygacil is currently unavailable in some EU countries. There are alternative treatment options and if you need Tygacil or are currently on Tygacil your doctor will prescribe an appropriate alternative. Patients who have any questions should speak to their doctor or pharmacist. Additional advice may be available from the national competent authority .

