



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
EMA/CHMP/515208/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Dificlir

fidaxomicin

On 12 December 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Dificlir. The marketing authorisation holder for this medicinal product is Astellas Pharma Europe B.V.

The CHMP adopted an extension to the existing indication for the film-coated tablets as follows:²

“DIFICLIR **film-coated tablets** is indicated ~~in adults~~ for the treatment of ~~Clostridium~~ ***Clostridioides difficile*** infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD) **in adult and paediatric patients with a body weight of at least 12.5 kg (see section 4.2 and 5.1).**

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

The CHMP also recommended approval of a new pharmaceutical form: Dificlir, granules for oral suspension (40 mg/ml). The granules for oral suspension are indicated for: “the treatment of *Clostridioides difficile* infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD) in adults and paediatric patients from birth to < 18 years of age (see section 4.2 and 5.1).

Consideration should be given to official guidelines 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

