

SUMMARY

fidaxomicin

DIFICLIR 200 mg

film-coated tablets

Modification of the listing conditions

Original French opinion adopted by the Transparency Committee on
14 February 2024

The legally binding text is the original French opinion version

Transparency Committee's conclusions**Clinical Benefit**

→ *Clostridium difficile* is responsible for 15 to 25% of cases of post-antibiotic diarrhoea and more than 95% of cases of pseudomembranous colitis. It is the leading cause of nosocomial diarrhoea in adults. In the past few years, the incidence, severity and mortality rates of *C. difficile* infections (CDI) have been increasing and this trend is related to the emergence of a particularly virulent strain. The mortality rates for *C. difficile* infection range from 0.6 to 1.5%, but reach 35 to 50% in the event of pseudomembranous colitis.

CDI is characterised by an increased risk of relapse (true recurrence or reinfection) within two months, that can be as high as 20 to 30%, despite well-managed antibiotic treatment. Factors associated with a high risk of recurrence include age over 65 years, the continuation of antibiotic therapy other than for CDI, severe comorbidity and renal impairment, more than one previous episode of CDI, the concomitant use of a PPI, and the severity of the initial disease.

- DIFICLIR (fidaxomicin) is part of a curative treatment regimen.
- Its efficacy/adverse effects ratio remains high.
- There is a therapeutic alternative recommended at the same stage of the care pathway (vancomycin).
- This product is a first-line treatment.

→ Public health benefit

DIFICLIR (fidaxomicin) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of DIFICLIR (fidaxomicin) 200 mg film-coated tablets remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of DIFICLIR (fidaxomicin) 200 mg film-coated tablets in the list of covered drugs for inpatients approved for use in the MA indication and dosages.

Clinical Added Value

The introduction of an alternative dosing regimen (extended-pulsed dosing) does not modify the previous conclusions of the Transparency Committee (CT). The Committee considers that DIFICLIR (fidaxomicin) 200 mg film-coated tablets maintains a moderate clinical added value (CAV III) in the treatment of *C. difficile* infections.