DIFICLIR™
fidaxomicin

C. differently

DIFICLIR™ and its active metabolite are potent inhibitors of *C. difficile* spore formation[1]

Indications: treatment of *C. difficile* infection (CDI), also known as *C. difficile*-associated diarrhoea (CDAD), in adults and paediatric patients with a bodyweight of at least 12.5 kg (film-coated tablets), in adults and paediatric patients from birth to <18 years of age (granules for oral suspension). Consideration should be given to official guidelines on the appropriate use of antibacterial agents.[2,3]

Prescribing information and information on adverse event reporting can be found on the back page.

This leaflet has been created by Tillotts Pharma.

ZERIA GROUP

TILLOTTS PHARMA

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C. difficile spores can persist in the hospital environment and act as a dangerous reservoir of infection[1]

Treatment with DIFICLIR™ is associated with reduced environmental *C. difficile* contamination compared with vancomycin and/or metronidazole[4]*

Methods:

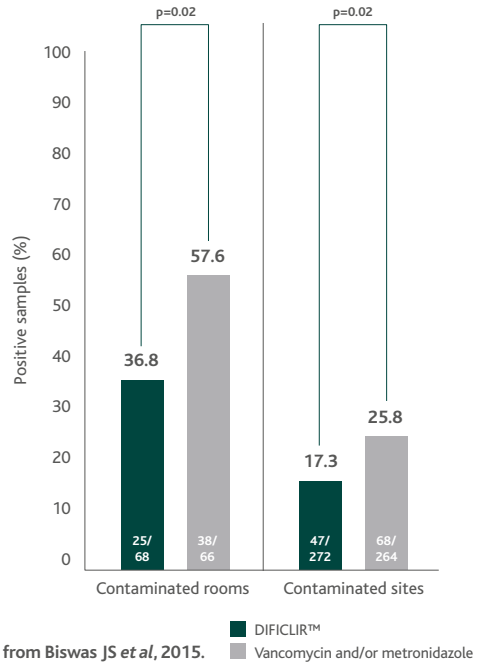
- Comparison of environmental contamination by *C. difficile* in the hospital rooms of CDI patients treated first-line with DIFICLIR™ (after October 2012) or vancomycin and/or metronidazole (before October 2012)
- Samples taken from four standardised areas in the patients' rooms and cultured for *C. difficile*

Patients:

- 68 hospitalised patients received DIFICLIR™ and 66 received vancomycin and/or metronidazole

DIFICLIR™
fidaxomicin

Environmental contamination rates for patients treated with DIFICLIR™ and vancomycin and/or metronidazole



Adapted from Biswas JS *et al*, 2015.

DIFICLIR™ demonstrated reduced surface contamination with *C. difficile* spores vs vancomycin and/or metronidazole in the real world[4]

With **DIFICLIR™** treatment, significantly lower spore counts were found on hospital room surfaces than with vancomycin and/or metronidazole treatment[4]*

The use of DIFICLIR™ in this study as a first-line agent for all patients with CDI was associated with a decrease in environmental contamination[4]*

CDI, *Clostridioides difficile* infection.

*This single centre study investigated whether DIFICLIR™ for treatment of all patients with CDI reduced *C. difficile* environmental contamination. Surfaces in the rooms of 68 hospitalised patients treated with DIFICLIR™ and 66 hospitalised patients treated with vancomycin and/or metronidazole were sampled. Patients treated with DIFICLIR™ were less likely to contaminate their environment (25/68, 36.8%) than patients treated with vancomycin and/or metronidazole (38/66, 57.6%) (p=0.02).[4]

DIFICLIR™ 200 mg film-coated tablets & 40 mg/ml granules for oral suspension – prescribing information

DIFICLIR™ fidaxomicin

DIFICLIR 200 mg film-coated tablets
Capsule-shaped tablets, white to off-white, debossed with "FDX" on one side and "200" on the other, each containing 200mg fidaxomicin.
DIFICLIR 40 mg/ml granules for oral suspension
Granules for oral suspension. White to yellowish white granules.
INDICATIONS: Treatment of *Clostridioides difficile* infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD). Tablets: in adult and paediatric patients with a body weight of at least 12.5 kg. Granules: in adults and paediatric patients from birth to < 18 years of age.
DOSAGE AND ADMINISTRATION:
Oral use.
Tablets: Adults and elderly standard dosing: 200 mg (one tablet) administered once every 12 hours for 10 days. DIFICLIR 40 mg/ml granules for oral suspension may be used in adult patients with difficulties in swallowing tablets. **Extended-pulsed dosing:** Fidaxomicin 200 mg tablets administered twice daily for days 1-5 (no intake of a tablet on day 6) then once daily on alternate days for days 7-25.
Children weighing at least 12.5 kg: 200 mg administered once every 12 hours for 10 days using the film-coated tablets or the granules for oral suspension. Reduced doses are recommended for patients with a body weight of less than 12.5 kg, see granules below. Tablets should be swallowed whole with water.
Granules: Adults and elderly standard dosing: 200 mg (5 ml) administered once every 12 hours for 10 days. **Extended-pulsed dosing**: Fidaxomicin 40 mg/ml granules for oral suspension (5 ml) administered twice daily for days 1-5 (no intake of suspension on day 6) then once daily on alternate days for days 7-25.
Children 12.5kg or over: 200 mg (5 ml oral suspension) once every 12 hours for 10 days.
Dose by bodyweight:

Table 1: Dosing instruction for the oral suspension Weight band of patient	Mg per dose (every 12 hours)	Volume of fidaxomicin oral suspension (every 12 hours)
< 4.0 kg	40 mg	1 ml
4.0 - < 7.0 kg	80 mg	2 ml
7.0 - < 9.0 kg	120 mg	3 ml
9.0 - < 12.5 kg	160 mg	4 ml
≥ 12.5 kg	200 mg	5 ml

For oral use (ingestion or via an enteral feeding tube using a syringe), with or without food. Caution in patients with severe renal impairment, moderate to severe hepatic impairment.
Reconstitution must be done by a healthcare professional. For instructions see Section 6.6 of the Summary of Product Characteristics. Oral suspension to be taken from the refrigerator 15 minutes prior to administration, shaken, and administered using the oral syringe and adaptor provided by the healthcare professional. Refrigerate after each use. Once reconstituted, use within 27 days.

Tablets and granules: If a dose is forgotten, take the missed dose as soon as possible, or if nearly time for the next dose, skip the missed dose.
CONTRAINDICATIONS: Hypersensitivity to the active substance or any excipients.
SPECIAL WARNINGS AND PRECAUTIONS: Reported: Hypersensitivity reactions including severe angioedema, discontinue immediately. Caution: in patients with a known macrolides allergy, patients with severe renal impairment or moderate to severe hepatic impairment, patients with pseudomembranous colitis, fulminant or life- threatening CDI, patients below 6 months of age. Not recommended/caution advised: Co-administration of potent P-glycoprotein inhibitors such as cyclosporine, ketoconazole, erythromycin, clarithromycin, verapamil, dronedarone and amiodarone is not recommended.
Testing for *C. difficile* colonization or toxin is not recommended in children younger than 1 year due to high rates of asymptomatic colonisation unless severe diarrhoea is present in infants with risk factors for stasis such as Hirschsprung disease, operated anal atresia or other severe motility disorders. Alternative aetiologies should always be sought and *C. difficile* enterocolitis be proven.
Granules: contains less than 1 mmol sodium (23 mg) per 5 ml suspension: essentially 'sodium-free'. Contains 2.5 mg sodium benzoate (E 211) in each ml oral suspension. May increase jaundice in babies up to 4 weeks old.
INTERACTIONS: Potent inhibitors of P-gp, such as cyclosporine, ketoconazole, erythromycin, clarithromycin, verapamil, dronedarone and amiodarone may increase Cmax and AUC of fidaxomicin. Fidaxomicin is a mild to moderate inhibitor of intestinal P-gp; e.g. digoxin, dabigatran etexilat. Paediatric population: no interaction data.
USE DURING PREGNANCY AND LACTATION: Pregnancy: no data available, not recommended. Breast-feeding: no data available, risk to the infant cannot be excluded. Discontinue breast-feeding or discontinue/abstain from fidaxomicin therapy. Animal data showed no effect on fertility.
UNDESIRABLE EFFECTS:
Common: vomiting (1.2%), nausea (2.7%) and constipation (1.2%). Uncommon: rash, pruritus, decreased appetite, dizziness, headache, dysgeusia, abdominal distention, flatulence, dry mouth. Frequency not known: hypersensitivity reactions (angioedema, dyspnea). Paediatric: profile as for adults, urticaria (2 cases) reported. Refer to Summary of Product Characteristics for details.
MA HOLDER: Tillotts Pharma GmbH, Warmbacher Strasse 80, DE-79618 Rheinfelden, Germany.
LEGAL CATEGORY: POM.
MARKETING AUTHORISATION NUMBER: Tablets EU/1/11/733/003-004. Granules EU/1/11/733/005.
DATE OF PREPARATION: July 2025.
FULL PRESCRIBING INFORMATION AVAILABLE ON REQUEST FROM THE MARKETING AUTHORISATION HOLDER OR FROM TILLOTTS PHARMA LIMITED, SPACES, 1ST FLOOR BUILDING 2, THE GREEN, DUBLIN AIRPORT CENTRAL, DUBLIN AIRPORT, SWORDS, COUNTY DUBLIN, K67 E2H3, TEL: (00 353 1) 294 2015. Dificlir® is a trademark.

Adverse events should be reported. Reporting forms and information can be found at HPRA Pharmacovigilance at www.hpra.ie - Adverse events should also be reported to Tillotts Pharma Ireland Ltd. Tel: +353 1 2942015

1. Babakhani F *et al.* Clin Infect Dis 2012;55:S162–169. 2. DIFICLIR™ 200 mg film coated tablets SmPC. 3. DIFICLIR™ 40 mg/ml granules for oral suspension SmPC. 4. Biswas JS *et al.* J Hosp Infect 2015;90:267–270.