CLINICAL UPDATE

Brand Name	Dificid®
Generic Name	fidaxomicin
Drug Manufacturer	Merck & Co, Cubist Pharmaceuticals

Clinical Update

TYPE OF CLINICAL UPDATE

New Formulation

FDA APPROVAL DATE

January 24, 2020

LAUNCH DATE

N/A

REVIEW DESIGNATION

Priority; Orphan

TYPE OF REVIEW

New Drug Application (NDA): 201699

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION(S) FOR USE

Dificid® is indicated in adult and pediatric patients 6 months of age and older for the treatment of C. difficile associated diarrhea.

MECHANISMS OF ACTION

Fidaxomicin is a macrolide antibacterial drug that inhibits RNA synthesis by binding to RNA polymerases. Fidaxomicin is bactericidal against C. difficile in vitro, and demonstrates a post-antibiotic effect vs. C. difficile of 6-10 hours.

DOSAGE FORM(S) AND STRENGTH(S)

- Film-coated tablets: 200 mg
- For oral suspension: 40 mg/mL (200 mg/5 mL) when reconstituted

DOSE & ADMINISTRATION

Adult Patient

The recommended dosage for adults is one 200 mg Dificid® tablet orally twice daily for 10 days.

Pediatric Patient

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Table 1: Recommended Dosage of DIFICID Oral Suspension in Pediatric Patients, Based on Weight

Body Weight	Dose Administered Twice Daily	Volume of 40 mg/mL Suspension to be Administered Orally Twice Daily
4 kg to less than 7 kg	80 mg	2 mL
7 kg to less than 9 kg	120 mg	3 mL
9 kg to less than 12.5 kg	160 mg	4 mL
12.5 kg and above	200 mg	5 mL

EFFICACY

The approval of Dificid® for the expanded indication was based on a randomized, comparative study in 148 pediatric patients 6 months to less than 18 years of age. Patients received Dificid® or vancomycin. The primary endpoints were clinical response and sustained response at 30 days post-treatment.

- The overall clinical response rate was 77.6% and 70.5% for Dificid® and vancomycin, respectively (difference of 7.5, 95% CI: -7.4, 23.9).
- The overall sustained response at 30 days post-treatment was 68.4% and 50.0% with Dificid® and vancomycin, respectively (difference of 18.4, 95% CI: 1.5, 35.3).