Dificid® (fidaxomicin) – Expanded orphan indication, New formulation

- On January 27, 2020, Merck announced the FDA approval of Dificid (fidaxomicin), in adult and pediatric patients aged 6 months and older for the treatment of *Clostridioides difficile*-associated diarrhea (CDAD).
    - Dificid was previously only approved in adults.
- In addition to the expanded indication, the FDA also approved a new oral suspension formulation of Dificid. It was previously only available as an oral tablet.
- 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).
- The most common adverse reactions (≥ 5%) with Dificid use in pediatric patients were pyrexia, abdominal pain, vomiting, diarrhea, constipation, increased aminotransferases, and rash.
- The recommended dosage of Dificid for pediatric patients weighing at least 12.5 kg and able to swallow tablets is one 200 mg Dificid tablet administered orally twice daily for 10 days. If unable to swallow tablets, pediatric patients may be dosed with Dificid oral suspension as recommended in the table below.

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

    - Refer to the Dificid drug label for dosing in adults.
- Merck's launch plans for Dificid oral suspension are pending. Dificid oral suspension will be available as a 40 mg/mL (200 mg/5 mL) strength when reconstituted.