REBYOTA™
(fecal microbiota, live-jslm) suspension, for rectal use

Fact Sheet

FIRST-IN-CLASS, FDA-APPROVED MICROBIOTA-BASED LIVE BIOTHERAPEUTIC

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About REBYOTA™ (fecal microbiota, live - jslm)

Approved by the U.S. Food and Drug Administration (FDA) on November 30, 2022, REBYOTA is indicated for the prevention of recurrence of *Clostridioides difficile (C. diff)* infection in individuals 18 years of age and older, following antibiotic treatment for recurrent *C. diff* infection.[1]

REBYOTA and the Gut Microbiome[1]

- REBYOTA is a pre-packaged single dose 150 mL microbiota suspension for rectal administration consisting of a liquid mix of up to trillions of live microbes—including *Bacteroides*. Each dose of REBYOTA is sourced from the stool of a single, qualified human donor and delivered directly to the gut microbiome.
- The most commonly reported (≥ 3%) adverse reactions occurring in adults following a single dose of REBYOTA were stomach pain (8.9%), diarrhea (7.2%), bloating (3.9%), gas (3.3%) and nausea (3.3%).

C. diff Infection and Recurrence

The *C. diff* bacterium causes debilitating symptoms, such as severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea and colitis (an inflammation of the colon).[2]

Around **HALF A MILLION INFECTIONS** are caused by *C. diff* every year[3,4]

Up to **THREE IN 10 PEOPLE** who get a *C. diff* infection will get it again[5,6,7,8]

After first recurrence, up to **SIX IN 10 PEOPLE** may get another *C. diff* infection[5,6]

Administration[1]

- REBYOTA is a single-dose treatment—administered during one visit at the doctor's office.
- Administration happens within minutes. Bowel cleansers, laxatives, anesthesia and colonoscopy are not required.
- Any antibiotic treatment prescribed for *C. diff* infection should be completed 1-3 days before administration of REBYOTA.

Please see Important Safety Information on page 2, and for full Prescribing Information, visit www.REBYOTA.com.

Clinical Trials

The efficacy and safety of REBYOTA was studied in the largest clinical trial program in the field of microbiome-based therapeutics, including five clinical trials with more than 1,000 participants.

Efficacy[9]

- The effectiveness of REBYOTA was established in a randomized, double-blind, placebo-controlled, multicenter Phase 3 study (Study 1), which formally integrated treatment success rates from a placebo-controlled Phase 2 study (Study 2) in a Bayesian analysis of the primary endpoint.
- The study enrolled 320 participants.
- The primary efficacy endpoint was the absence of *C. diff* infection diarrhea for eight weeks after study treatment.
- The model-estimated treatment success rate was 70.6% in the REBYOTA group and 57.5% in the placebo group, demonstrating a 99.1% posterior probability that REBYOTA was superior to placebo.

Safety and Manufacturing

- Adverse events (AEs) were primarily mild-to-moderate and there were no treatment-related serious adverse events (SAEs). Through six months after blinded treatment, incidence of treatment-emergent adverse events (TEAEs) was higher in REBYOTA recipients compared with placebo (55.6%, n=100/180, REBYOTA; 44.8%, n=39/87, placebo), mostly driven by a higher incidence of mild gastrointestinal events.[9]
- REBYOTA is sourced from qualified donors and the source material is tested for a broad panel of transmissible pathogens.
- The donor program has systems in place to monitor test results and emerging threats as part of the commitment to patient safety.

For more information, visit www.REBYOTA.com.

INDICATION

REBYOTA (fecal microbiota, live - jslm) is indicated for the prevention of recurrence of *Clostridioides difficile (C. diff)* infection in individuals 18 years of age and older, following antibiotic treatment for recurrent *C. diff* infection.

Limitation of Use

REBYOTA is not indicated for the treatment of *C. diff* infection.

IMPORTANT SAFETY INFORMATION

- You should not receive REBYOTA if you have a history of a severe allergic reaction (e.g., anaphylaxis) to REBYOTA or any of its components.
- You should report to your doctor any infection you think you may have acquired after administration.
- REBYOTA may contain food allergens.
- Most common side effects may include stomach pain (8.9%), diarrhea (7.2%), bloating (3.9%), gas (3.3%), and nausea (3.3%).
- REBYOTA has not been studied in patients below 18 years of age.
- Clinical studies did not determine if adults 65 years of age and older responded differently than younger adults.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch, or call **1-800-332-1088**.

Please click to see the full Prescribing Information.

FERRING PHARMACEUTICALS

Microbiome Therapeutics Development

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1. REBYOTA. Prescribing information. Parsippany, NJ: Ferring Pharmaceuticals Inc; 2022. **2.** Centers for Disease Control and Prevention. What Is *C. Diff*? 17 Dec. 2018. Available at: https://www.cdc.gov/cdiff/what-is.html **3.** Cornely OA, Miller MA, Louie TJ, Crook DW, Gorbach SL. Treatment of first recurrence of *Clostridium difficile* infection: fidaxomicin versus vancomycin. Clin Infect Dis. 2012;55(suppl 2):s154-s161. **4.** Guh AY, Mu Y, Winston LG, et al, for the Emerging Infections Program *Clostridioides difficile* Infection Working Group. Trends in U.S. burden of *Clostridioides difficile* infection and outcomes. N Engl J Med. 2020;382(14):1320-1330. **5.** Smits WK, Lyras D, Lacy DB, Wilcox MH, Kuijper EJ. *Clostridium difficile* infection. Nat Rev Dis Primers. 2016;2(16020): 1-47. **6.** Kelly CP. Can we identify patients at high risk of recurrent *Clostridium difficile* infection? Clin Microbiol Infect. 2012;18(suppl 6):21-27. **7.** Riddle DJ, Dubberke ER. *Clostridium difficile* infection in the intensive care unit. Infect Dis Clin North Am. 2009;23(3):727-743. **8.** Nelson WW, et al. Health care resource utilization and costs of recurrent *Clostridioides difficile* infection in the elderly: a real-world claims analysis. J Manag Care Spec Pharm. 2021;27(7):828-838. doi: 10.18553/jmcp.2021.20395. Epub 2021 Mar 11. **9.** Khanna, S., Assi, M., Lee, C. et al. Efficacy and safety of RBX2660 in PUNCH CD3, a Phase III, randomized, double-blind, placebo-controlled trial with a Bayesian primary analysis for the prevention of recurrent *Clostridioides difficile* infection. Drugs (2022). Available at: https://doi.org/10.1007/s40265-022-01797-x.