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 Microbiome1

- 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

**Fact Sheet**

**For Media Inquiries:** US.communications@ferring.com

**Administration1**

- 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

- 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 *Clostridioides difficile* (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.

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](https://www.FDA.gov/medwatch), or call 1-800-332-1088.

Please click to see the full Prescribing Information.