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

DDW PRODUCT THEATER

RISE ABOVE RECURRENT *C. DIFFICILE* INFECTION with REBYOTA™

The first FDA-approved microbiota-based live biotherapeutic to prevent recurrence of *C. difficile* infection starting at first recurrence[1,2,a]

[a]In the pivotal phase 3 trial, 32.8% of patients were treated at first recurrence of CDI following antibiotic treatment of CDI.[1]

FEATURING:

Caterina Oneto, MD
Clinical Assistant Professor
NYU Division of Gastroenterology
Board Certified in Gastroenterology

McCORMICK PLACE
PRODUCT THEATER 1 (EXHIBIT HALL)
SUNDAY, MAY 7, 2023 • 9:30 AM–10:15 AM

LEARNING OBJECTIVES:

- Understand the microbial composition, potency, and standardized manufacturing process of REBYOTA
- Review the efficacy and safety data for REBYOTA
- Discuss the use of REBYOTA in clinical practice

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INDICATION

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

Limitation of Use

REBYOTA is not indicated for treatment of CDI.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer REBYOTA to individuals with a history of a severe allergic reaction (eg, anaphylaxis) to any of the known product components.

Warnings and Precautions

Transmissible infectious agents

Because REBYOTA is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Any infection suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Ferring Pharmaceuticals Inc.

Management of acute allergic reactions

Appropriate medical treatment must be immediately available in the event an acute anaphylactic reaction occurs following administration of REBYOTA.

Potential presence of food allergens

REBYOTA is manufactured from human fecal material and may contain food allergens. The potential for REBYOTA to cause adverse reactions due to food allergens is unknown.

Adverse Reactions

The most commonly reported (≥3%) adverse reactions occurring in adults following a single dose of REBYOTA were abdominal pain (8.9%), diarrhea (7.2%), abdominal distention (3.9%), flatulence (3.3%), and nausea (3.3%).

Use in Specific Populations

Pediatric Use

Safety and efficacy of REBYOTA in patients below 18 years of age have not been established.

Geriatric Use

Of the 978 adults who received REBYOTA, 48.8% were 65 years of age and over (n=477), and 25.7% were 75 years of age and over (n=251). Data from clinical studies of REBYOTA are not sufficient to determine if adults 65 years of age and older respond 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 scan QR code or visit www.REBYOTAHCP.com for full Prescribing Information.

References

1. REBYOTA. Prescribing information. Parsippany, NJ: Ferring Pharmaceuticals Inc; 2022.
2. US Food and Drug Administration. FDA Approves First Fecal Microbiota Product. https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecalmicrobiota-product. Accessed December 1, 2022.

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