# REBYOTA® (fecal microbiota, live-jslm) DOSING CHECKLIST

Use this REBYOTA Dosing and Administration checklist to keep on hand as you prepare for your patient's administration appointment.

## DOSING TIMELINE

The REBYOTA Dosing Timeline shows the important steps you need to take prior to your patient's administration day. This dosing timeline is for example purposes only and is subject to changes depending on benefits verification, site of care availability, and patient needs.

| DAY 1 DATE | DAY 2 DATE | DAY 3 DATE | DAY 4 DATE | DAY 5 DATE | DAY 6 DATE |
|---|---|---|---|---|---|
| **ORDER**<br>Best practice is to order REBYOTA 5 days prior to scheduled administration date | **DELIVERY**<br>• REBYOTA is typically delivered next day[a]<br>• Once you receive your delivery, you have two options:<br>– Option 1: Leave REBYOTA within unopened orange shipper box for up to 5 days<br>– Option 2: Follow unpacking instructions for proper storage<br>[a]Orders placed Friday by 3:00 PM ET will arrive Tuesday. | **CONFIRM**<br>Confirm patient has completed antibiotics 24-72 hours prior to their administration appointment | **NO ANTIBIOTICS** | **THAW**<br>Begin thawing REBYOTA 24 hours before administration[b]<br>[b]REBYOTA can be stored in a refrigerator (2°C to 8°C, 36°F to 46°F) for up to 5 days (including thaw time). | **ADMINISTER**<br>Administer REBYOTA |
| | **DAYS 1-3**<br>**COMPLETE ANTIBIOTICS** | | | | |

No bowel prep/laxatives, fasting, anesthesia, or colonoscopy required.

**To learn more about REBYOTA, please visit www.REBYOTAHCP.com or scan the QR code.**

## 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%).

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

# REBYOTA® ADMINISTRATION CHECKLIST

## PREPARE FOR APPOINTMENT

- ☐ Thaw REBYOTA completely by placing in a refrigerator, 2°C to 8°C (36°F to 46°F), for approximately 24 hours or store in the refrigerator and use within 5 days, including thawing time
- ☐ Gather supplies:
  - Included: REBYOTA and administration set
  - Not included: water-soluble lubricant and disposable underpad

## BEFORE

- ☐ Request that patient empty bladder and bowel, if possible
- ☐ Place patient in the preferred position: either a left-side or knee-chest position

## DURING

- ☐ Lubricate and insert administration tube about 5 inches pointed slightly toward navel
- ☐ Hold the administration tube, with other hand open pinch clamp
- ☐ Gradually raise, allow REBYOTA to flow via gravity

## AFTER

- ☐ Withdraw tube
- ☐ Keep patient in position for up to 15 minutes to minimize possible cramping
- ☐ It is normal for some product to remain in tube; does not affect administration
- ☐ No specified cleaning of facility in phase 3 trial protocol

## IMPORTANT CONSIDERATIONS

- **DO NOT** administer REBYOTA during antibiotic treatment for CDI
- Administer REBYOTA **24 to 72 hours** after the last dose of antibiotics

## TIPS FOR YOU AND YOUR PATIENT

Keep in mind these helpful tips to ensure a positive REBYOTA experience.

### FOR YOU

- Keep REBYOTA in the refrigerator until patient arrives
- Keep REBYOTA in the opaque wrapper for patient comfort
- **DO NOT** prime tubing; air is ok in the tube
- Tube is clearly marked with black insertion line
- **DO NOT** lubricate the two holes on the tube
- **DO NOT** squeeze bag or place on IV pole

### FOR YOUR PATIENT

- Explain that administration will feel cool
- Advise patient to hold in REBYOTA following administration
- Recommend adult protective underwear
- Talk to your doctor before taking antibiotics for any reason for 8 weeks after administration of REBYOTA

**Visit www.REBYOTAHCP.com to see the Full Instructions for Use.**

**Scan the QR code to watch the REBYOTA Administration Video.**

## IMPORTANT SAFETY INFORMATION

**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 click here for full Prescribing Information.**

FERRING PHARMACEUTICALS
Microbiome Therapeutics Development

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