

CLINICIAN INFORMATION

Brief Summary Instructions

Regulora® Prescription Digital Therapeutic

This clinician information leaflet does not include all the information needed to use Regulora safely and effectively. Please see the full Regulora Instructions for Use.

INDICATIONS FOR USE

Regulora® is a prescription-only digital therapeutic device intended to provide behavioral therapy through gut-directed hypnotherapy for adults 22 years of age and older who have been diagnosed with irritable bowel syndrome (IBS). Regulora is indicated as a 3-month treatment for patients with abdominal pain due to IBS and is intended to be used together with other IBS treatments.

SAFETY INFORMATION

US federal law restricts this mobile application device to sale by or on the order of a physician.

Regulora is not for everyone, and not all patients will achieve relief from their IBS symptoms.

- Regulora may not be appropriate for patients with mental or physical impairment that would prevent interacting with a mobile video application
- Regulora may not be appropriate for patients with evidence of intestinal illness that better explain IBS symptoms such as celiac disease or inflammatory bowel disease
- Regulora should not be used in lieu of current IBS medication or therapy
- In a controlled clinical trial, Regulora was not associated with any treatment-related serious adverse events. Non-serious adverse events possibly related to treatment included headache (0.5%, n=1), fatigue (0.5%, n=1), abdominal pain (0.5%, n=1), and constipation (0.5%, n=1)
- Patients should be instructed to contact their healthcare provider if they experience worsening of their IBS symptoms, headache, or fatigue during or after Regulora treatment, or if they experience feelings or thoughts of harming themselves or others

WHAT IS REGULORA?

Regulora is a digital therapeutic mobile app that is downloaded onto a mobile device. Regulora provides 12 weeks of remote behavioral therapy based on gut-directed hypnotherapy (GDH). Prior to Regulora, GDH would be provided via a trained clinician in a medical clinic. With Regulora, pre-recorded GDH treatment sessions are presented on a mobile device online. The Regulora app provides your patient with

7 streamed GDH sessions over 3 months. Each treatment session takes approximately 30 minutes. There are also 15-minute practice sessions that your patient can take between treatment sessions.

WHO SHOULD USE REGULORA?

Your patient should only use Regulora if they

- Are 22 years or older with IBS
- Speak and read English
- Have regular access to a mobile device (such as a smartphone or tablet) with internet access
- Are under the supervision of a healthcare provider

BENEFITS OF REGULORA

Regulora was evaluated in a multisite, randomized, controlled, blinded clinical trial of 362 adults with Rome IV-diagnosed IBS. Patients were randomized to receive 12 weeks of treatment with Regulora or a digital muscle relaxation control. During a 4-week post-treatment period, 30.4% of subjects in the Regulora group and 27.1% of the subjects in the control group experienced at least a clinically meaningful 30% reduction in abdominal pain (abdominal pain response). Although the difference between treatment groups during this post-treatment period was not statistically significant, significantly more patients treated with Regulora (29.3%) were abdominal pain responders compared to those in the control treatment group (18.8%) during the 12-week on-treatment period.

Following 12 weeks of treatment, patients treated with Regulora experienced other clinically meaningful improvement in IBS symptoms:

- 44.9% experienced at least a 30% improvement in the proportion of stools with normal consistency, based on Bristol Stool Form Scale definitions
- 50.3% were either a pain or stool responder as defined above
- 64% experienced adequate relief of their symptoms

Further, 87.2% of subjects would recommend Regulora to someone else with IBS, indicating satisfaction with the Regulora app user experience.

REGULORA PRESCRIPTIONS

Dose and Frequency

Patients should be instructed to complete all 7 treatment sessions over the 3-month treatment period. If an interruption occurs while viewing a session, that session must be restarted and completed from the beginning. Patients have the option to start again 3 times for each session.

After completing each treatment session, patients will have access to 15-minute practice sessions until the next scheduled treatment.

Duration and Extension

Patient access to Regulora will automatically discontinue after 3 months. The prescription will end automatically based on the start date.

SECURITY

Please remind patients that it is their responsibility to secure their mobile devices (smartphones or tablets) by adhering to the following recommendations:

- Password/PIN protect the mobile device
- Never share mobile device or Regulora log-in information (account or password). Note that metaMe will never request your patient's password and should be notified immediately if you receive an email or phone call requesting Regulora log-in information
- Set the mobile device to automatically lock after several minutes of inactivity
- Avoid connecting to untrusted and/or unsecure WiFi networks
- Regularly install the periodic updates to the mobile device operating system to ensure latest malware/antivirus protection
- Do not use "jail-broken" mobile devices
- Notify metaMe if any type of cybersecurity incident related to Regulora is suspected

DOWNLOADING AND STARTING REGULORA

After you write a prescription for Regulora, your patient will be provided an Access Code. This code will be used to access Regulora. To begin therapy:

- Search for Regulora from metaMe Health on the Apple App Store or Google Play Store
- Download and install Regulora
- Open the Regulora app on the mobile device and follow the instructions to set up an account and access Regulora with the Access Code
- Follow the on-screen instructions to schedule 7 Regulora treatment sessions over the following 3 months

COMPATIBLE DEVICES

Regulora is compatible with smartphones, tablets, and other mobile devices that are connected to the internet. Use of a Wi-Fi or cellular data network with a minimum speed of 2 Mbps (eg, 3G) should be used to access treatment, although 5 Mbps or greater (eg, 4G/LTE, 5G, or Wi-Fi) is recommended.

Minimum Device Requirements for Regulora

	iOS Devices	Android Devices
Operating system	iOS 12.4 or later	Android 9 or later
Processor minimum	1.4 GHz	1.8 GHz
Memory (RAM) minimum	1 GB	2 GB
Examples of minimally compatible devices	iPhone 6 or later, iPad Air 2, and iPad Mini 4 or later	Samsung Galaxy 8 and Motorola Moto G7 or later

ADDITIONAL SUPPORT

For additional technical support with any aspect of the Regulora app, your patients can contact metaMe Health at 888-463-8263 or help@regulora.com.

metaMe Health

metaMe Health, Inc.
222 W. Merchandise Mart Plaza
Suite 1230
Chicago, IL 60654

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