

PATIENT INFORMATION

Brief Summary Instructions

Rx Only

CAUTION: Federal law restricts this device to sale by or on the order of a Physician.

MAHANA™ IBS

Prescription Digital Therapeutic Mobile Application

This patient information leaflet does not include all the information needed to use Mahana IBS safely and effectively. Please see full Patient Directions for Use within the *Profile* section of the Mahana IBS mobile application for complete Important Safety Information.

Important Safety Information:

Warnings/precautions: Do not use Mahana IBS to communicate any emergency, urgent or critical information. Mahana IBS does not include features that can send alerts or warnings to your clinician.

Users should seek medical care if they have feelings or thoughts of harming themselves or others while using Mahana IBS. If you have feelings or thoughts of harming yourself or others, please dial 911 or go to the nearest emergency room.

The ability to use Mahana IBS may be limited for patients who are visually impaired.

Mahana IBS is not intended to be used as a standalone treatment for Irritable Bowel Syndrome (IBS). Mahana

IBS does not replace care by your provider and is not intended to be a substitute for other IBS treatments you may be taking. You should continue to take your medications as directed by your provider.

In order to use Mahana IBS, you must be able to read and understand English, have a mobile phone or tablet with internet connectivity, and be familiar with the use of mobile applications.

What is Mahana IBS?

Mahana IBS is a Prescription Digital Therapeutic (PDT) mobile application designed to deliver Cognitive Behavioral Therapy (CBT) to patients with Irritable Bowel Syndrome (IBS). Scientific research has revealed that there are complex communication loops between the central nervous system (the brain and spinal cord) and enteric nervous system (the gut or 'second brain'). CBT allows you to influence the communication between them in order to reduce the severity of IBS.

Your licensed healthcare provider will prescribe the Mahana IBS mobile application if appropriate for you. Mahana IBS is available by prescription only for adults, aged 22 years of age and older, with IBS. Mahana IBS is intended to be used together with other IBS treatments you may be using. The Mahana IBS mobile application is accessible from your mobile phone or tablet.

How to Start Using Mahana IBS:

The following steps will help guide your use of Mahana IBS:

- Your clinician will prescribe Mahana IBS and you will be contacted by email with an access link for the Mahana IBS mobile application. You must use this access link to access the Mahana IBS mobile application.
- You will use your email address to access the Mahana IBS mobile application.

- Next, you need to set a password that is a minimum of 8 characters, contains no sequential or repetitive characters (such as 12345 or aaaaa), and is not a commonly used dictionary word.
 - Once your password is set, you can then begin working and learning with Mahana IBS. This includes completing sessions, answering questions, and reporting about your symptom severity.
 - Mahana IBS incorporates review screens such that, as you progress through the modules, you may review data entered earlier in the program.
 - It is expected that you will complete the 10 sessions of the program within 12 weeks.
 - After 90 days from the start of therapy, the application will no longer allow progression or unlock new content. However, you may access existing content previously unlocked.
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Please see full Patient Directions for Use for complete instructions on how to use Mahana IBS.

Mahana IBS is optimized for mobile devices (phone/tablet) access and is supported on the following mobile operating systems:

- iOS
 - Android
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General Information About the Safe and Effective Use of Mahana IBS:

Mahana IBS is meant to be used in conjunction with your ongoing IBS treatment. There are no contraindications to using Mahana IBS.

Please see full Patient Directions for Use in the Mahana IBS application for complete Important Safety Information.

Indications for Use Statement:

Mahana IBS is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy for adults aged 22 years of age and older who have been diagnosed with Irritable Bowel Syndrome (IBS). Mahana IBS is indicated as a 3 month treatment for patients with IBS. Mahana IBS treats IBS by reducing the severity of symptoms and is intended to be used together with other IBS treatments.

Summary of Clinical Testing:

Mahana IBS has been studied in a randomized, controlled trial in 558 patients with IBS. Patients with mild to severe IBS (IBS-Symptom Severity Scale [IBS-SSS] ≥ 75) were randomly assigned to one of three treatment groups: Treatment-as-Usual (TAU), Therapist-delivered Cognitive Behavioral Therapy (TCBT) via telephone, or Web-based CBT (Mahana IBS). At Month 3, group mean changes in IBS-SSS scores were reduced in the Mahana IBS group vs. TAU, and met the minimum clinically-important difference (MCID) of 50 points as defined for the IBS-SSS by Francis *et al.* The frequency of related, treatment-emergent adverse events (TRAEs) revealed no notable differences between treatment groups. The full clinical study summary is also available in the publication.

Additional Support Available:

For additional technical support with any aspect of the Mahana IBS application, you can contact Mahana via email at support@mahanatx.com or by phone at
1-844-MAHANA-0
1-844-624-2620

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