

PATIENT INFORMATION

Brief Summary Instructions

Rx Only

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

Parallel™ Prescription Digital Therapeutic Software

This patient information leaflet does not include all the information needed to use Parallel safely and effectively. Please see full Patient Directions for Use within the Help section of the Parallel web application for complete Important Safety Information.

Important Safety Information:

Warnings/precautions: Do not use Parallel to communicate any emergency, urgent or critical information. Parallel 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 Parallel. 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 Parallel may be limited for patients who are visually impaired.

Parallel is not intended to be used as a standalone treatment for Irritable Bowel Syndrome (IBS). Parallel 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 Parallel, you must be able to read and understand English, have a desktop or laptop computer with a web browser and internet connectivity, and be familiar with the use of web applications.

What is Parallel?

Parallel is a Prescription Digital Therapeutic (PDT) web 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 Parallel web application if appropriate for you. Parallel is available by prescription only for adults, aged 22 years of age and older, with IBS. Parallel is intended to be used together with other IBS treatments you may be using. The Parallel web application is accessible from your desktop or laptop computer's browser.

How to Start Using Parallel:

The following steps will help guide your use of Parallel:

- Your clinician will prescribe Parallel and you will be contacted by email with an access link for the Parallel web application. You must use this access link to enter the Parallel web application.
- You will first create a username to access the Parallel web application. We recommend that you choose a username that is easy for you to remember but does not contain any personally identifiable information.
- 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 Parallel. This includes completing sessions, answering questions, and reporting about your symptom severity.
- Parallel 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 8 sessions of the program within 12 weeks.
- After 90 days from start of therapy, the application will no longer allow progression or unlock new content. However, you may access existing content previously unlocked.

Please see full Patient Directions for Use for complete instructions on how to use Parallel.

Parallel is optimized for computer (desktop/laptop) access and is supported on the following computer operating systems and web browsers:

- MacOS: Safari, Chrome, Firefox
- Windows: Chrome, Firefox

General Information About the Safe and Effective Use of Parallel:

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

Please see full Patient Directions for Use in the Parallel website for complete Important Safety Information.

Indications for Use Statement:

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

Summary of Clinical Testing:

Parallel 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 (Parallel). At Month 3, group mean changes in IBS-SSS scores were reduced in the Parallel 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 Parallel web application, you can contact Mahana via email at support@mahanatherapeutics.com or by phone at 1-844 MAHANA-0 (1-844-624-2620).

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