

PATIENT INFORMATION

Brief Summary Instructions

reSET-O[®]

Prescription Digital Therapeutic Software

This patient information leaflet does not include all the information needed to use reSET-O safely and effectively. Please see full Patient Directions for Use within the reSET-O app for complete Important Safety Information.

Indications for Use Statement:

reSET-O is intended to increase retention of patients with Opioid Use Disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

Important Safety Information

Warnings/Precautions:

Safety:

Do not use reSET-O to communicate any emergency, urgent or critical information.

reSET-O does not include features that can send alerts or warnings to your clinician.

If you have feelings or thoughts of harming yourself or others, or in case of emergency, please dial 911 or go to the nearest emergency room.

reSET-O is not intended to be used as stand-alone therapy for Opioid Use Disorder (OUD) and does not replace care by your provider.

reSET-O is not a substitute for your medications. You should continue to take your medications as directed by your medical provider.

reSET-O is not intended to replace outpatient treatment.

Effectiveness:

The buprenorphine notification feature is voluntary and must be set up correctly by you, if you wish to receive accurate daily notifications.

The long-term benefit of using reSET-O has not been evaluated in studies with buprenorphine lasting beyond 12-weeks (84 days) in the OUD population.

The ability of reSET-O to prevent potential relapse after therapy discontinuation has not been studied.

Patient Eligibility:

reSET-O should only be used by individuals who are enrolled or participating in an OUD treatment program. It should be used with outpatient clinician treatment, buprenorphine treatment, and contingency management (a program that provides incentives for achieving behavior goals).

reSET-O is intended for patients whose primary language is English

You should have access to an Android/iOS tablet or smartphone and be familiar with the use of smartphone applications (apps).

You should be able to upload data periodically, i.e., have internet/wireless connection access

Security:

reSET-O requires you to enter a user name and password prior to use. Please do not share your user name and password with others.

reSET-O may contain and transmit protected health information and/or personally identifiable information.

What is reSET-O?

reSET-O is a Prescription Digital Therapeutic (PDT) for patients with Opioid Use Disorder. The reSET-O mobile application is downloadable onto your mobile device. Your licensed healthcare provider will prescribe reSET-O if it is appropriate for you. reSET-O is meant to be used in between your in-office therapy sessions. Your provider will explain how you should use reSET-O.

How to Start Using reSET-O:

The following steps will help guide your use of reSET-O:

- Your clinician will prescribe reSET-O and you will be contacted by a patient care specialist from reSET Connect™ by Pear Therapeutics, Inc.
- The patient care specialist will guide you through downloading the reSET-O app from the Apple App Store or Google Play Store on your smartphone and tablet, and then provide you with an access code that you will enter into the app, along with the email address that you shared with your doctor. You must have this access code to use reSET-O.
- Next, you need to set a password that is at least 8 characters in length and includes one capital letter and a special character (i.e. !, @, #, \$, %, ., ^, *, (), +, =, ? >, <) You will only need this password if you need to delete/reinstall the app or get a new phone or tablet.
- Once your password is set, you can then begin working and learning with reSET-O. This includes completing lessons, answering quiz questions, reporting medication usage and reporting your substance use, cravings, and triggers.
- reSET-O uses positive reinforcement to encourage your progress, including the lessons you complete and the results of your drug screens.
- During the 12-week (84 day) therapy period, you will continue to see your clinician, who will review your progress using the app and data you have reported.

Please see full Patient Directions for Use for complete instructions on how to use reSET-O and how to share information with your clinician.

What Operating Systems and Browsers Does reSET-O Support?

The reSET-O app is supported on the following mobile operating systems:

- iOS
- Android

General Information about the Safe and Effective Use of reSET-O:

You should only use reSET-O if enrolled in an OUD treatment program. reSET-O is meant to be used in conjunction with in-office therapy sessions with your OUD clinician. reSET-O is not intended to replace or reduce the frequency or duration of in-person therapy. There are no contraindications to using reSET-O.

Please see full Patient Directions for Use for complete Important Safety Information.

Additional Information Available:

The clinical study summary is available in publication¹ and a summary of the clinical study results is available on the FDA website.²

Additional Support Available:

For additional support with any aspect of the reSET-O app, contact PearConnect™ via email at support@pearconnect.com or by phone at 1-833-697-3738.

Rx Only