

PATIENT INFORMATION

Brief Summary Instructions

reSET® Prescription Digital Therapeutic Software

This patient information leaflet does not include all the information needed to use reSET safely and effectively. Please see full Directions for Use (within the software application) for complete important safety information.

Important Safety Information:

Warnings/precautions: reSET is not to be used to communicate any urgent, critical or emergent information. reSET does not include features that can send alerts or warnings to your Clinician. reSET is not to be used for emergencies. If you have feelings or thoughts of harming yourself or others, please dial 911 or go to the nearest emergency room.

reSET is intended for patients whose primary language is English and who have access to an Android/iOS tablet or smartphone and are familiar with use of mobile apps (applications). Patients should be able to upload data periodically, i.e. have internet/wireless connection access.

reSET requires you to enter a user name and password prior to use. Please do not share your user name and password with others. reSET may contain and transmit protected health information and/or personally identifiable information.

The long-term benefit of treatment with reSET on abstinence has not been evaluated in studies lasting beyond 12-weeks in the substance use disorder (SUD) population. The ability of reSET to prevent potential relapse after treatment discontinuation has not been studied. The safety and effectiveness of reSET has not been established in patients enrolled in opioid treatment programs.

What is reSET?

reSET is a prescription digital therapeutic — the first of its kind to be granted marketing authorization by the U.S. FDA.

reSET is a software app to treat patients with substance use disorder (SUD) and requires a prescription from a licensed healthcare provider (HCP). It's intended to provide cognitive behavioral therapy to be used in conjunction with outpatient treatment under the supervision of a clinician for patients 18 years of age or older. reSET delivers 12 weeks of treatment on demand through your smartphone or tablet device.

How to Start Using reSET:

The following steps will help guide your use of reSET:

- Your doctor will prescribe reSET and you will be contacted by Pear CONNECT. They will guide you through downloading the reSET App from the Apple App Store or Google Play Store on your smartphone and tablet. They will 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.
- 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 delete/reinstall the app or get a new phone or tablet.
- Once your password is set, now you can begin working and learning with reSET. This includes completing lessons, answering quiz questions, and reporting your substance use, cravings, and triggers.
- reSET uses positive reinforcement to encourage your progress, including the lessons you complete and any results of your drug screen testing. Talk to your HCP to learn more about reSET.
- During the 12 weeks treatment period, you will continue to see your doctor who will review your progress using the app and data you have reported.

Please see full Directions for Use for complete instructions on how to use reSET and how to share information with your healthcare provider.

What Operating Systems Does reSET Support?

- iOS 8.0 and above
 - Android 4.1 and above
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General Information About the Safe and Effective Use of reSET:

reSET should only be used by individuals who are enrolled or participating in an SUD treatment program. It should be used with face-to-face counseling and contingency management. It is not intended to replace outpatient treatment. reSET is not intended to be used as a stand-alone therapy for SUD and does not replace care by a licensed medical provider. reSET does not substitute for medication. You should continue to take your medications as directed by your physician or medical provider. The tracking data collected by reSET is not intended to be used as a stand-alone assessment of treatment progress. There are no contraindications to using reSET.

Please see full Directions for Use for complete important safety information.

Indications for Use Statement:

reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12-week (90-days) prescription-only treatment for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse.

It is intended to:

- increase abstinence from a patient's substances of abuse during treatment, and
 - increase retention in the outpatient treatment program.
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Additional Support Available:

For additional support with any aspect of the reSET software app, you can contact Pear Therapeutics' Patients Services Center via email at support_reset@peartherapeutics.com or by phone at 1-833-MY-RESET (1-833-697-3738).



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