CLINICIAN INFORMATION
Brief Summary Instructions

Somryst®
Prescription Digital Therapeutic

This clinician information leaflet does not include all the information needed to use Somryst safely and effectively. Please see the full Clinician Directions for Use within the clinician dashboard for complete Instructions and Important Safety Information.

Indications for Use Statement:

Somryst is a prescription-only digital therapeutic intended to provide a neurobehavioral intervention (CBT-I) to patients 22 years of age and older with chronic insomnia. Somryst treats patients with chronic insomnia by improving a patient's insomnia symptoms.

Who Should Use Somryst?

Your patient should use Somryst if they:
- Are 22 or older with chronic insomnia
- Are able to read and understand English
- Have regular access to a mobile device (such as smartphone or tablet)
- Are familiar with how to use mobile apps (applications)
- Are able to upload data periodically.
- Are under the supervision of a Health Care Provider

Who Should Not Use Somryst? (Contraindications)

Somryst uses sleep restriction and consolidation, limiting the time a patient spends in bed to match the amount of time they sleep. This treatment technique can increase risks to some patients whose pathophysiology may be worsened. Because of this, it is not appropriate for everyone.

Patients with the following conditions or disorders should not use Somryst:
- Any disorder exacerbated by sleep restriction (e.g. bipolar disorder, schizophrenia, other psychotic spectrum disorders)
- Untreated obstructive sleep apnea
- Parasomnias
- Epilepsy
- Individuals at high risk of falls
- Individuals who are pregnant
- Individuals who have any other unstable or degenerative illness judged to be worsened by sleep restriction delivered as part of CBT-I

Safety Warnings

Somryst is not for everyone. Please use your clinical judgment to determine whether Somryst is right for your patient.
- Somryst is not for emergency use. Please instruct patients to dial 911 or go to the nearest emergency room in the event of a medical emergency.
- Patients should be clearly instructed not to use Somryst to communicate severe, critical, or urgent information to their Health Care Providers.
- Somryst is meant to be used as treatment with supervision of a Health Care Provider.
- Somryst is not meant to be a substitute for any treatment medication.
- Somryst contains sensitive medical information. Please instruct patients to protect their information by password-protecting their smartphone or tablet, and ensuring no one else may access their device
- Sleep Restriction (and Consolidation) within Somryst can cause sleepiness, especially in the early stages of using the PDT. Somryst should not be used if the patient needs to be alert or cautious to avoid serious accidents in their job or daily life. Examples include:
  - Long-haul truck drivers
  - Long-distance bus drivers
  - Air traffic controllers
  - Operators of heavy machinery
  - Some assembly line jobs
- The usage data collected in therapy lessons by Somryst are not intended to be used as a standalone assessment of treatment progress.

Note: In the early stages of treatment, increased daytime sleepiness may be expected, but is usually temporary. Please instruct the patient to consult with their Health Care Provider if these experiences do not go away over a few weeks, as it may indicate that they have another sleep disorder or medical condition other than insomnia. Please instruct the patient that if they have trouble staying awake while performing potentially dangerous tasks (like driving) at any point in the treatment, to avoid these dangerous tasks or stop following the sleep restriction component of the therapy.

Please instruct the patient to read and follow the instructions provided in each module, and to stay with the therapy until the end to achieve the best results with Somryst. Please instruct the patient that it is important to give honest and accurate answers when reporting sleep results.

What is Somryst?

Somryst is a 9-week Prescription Digital Therapeutic (PDT) for chronic insomnia. Somryst can be used on a mobile device, such as a smartphone or tablet. Somryst is available by prescription only. A licensed Health Care Provider (HCP) must prescribe Somryst and use of Somryst should be undertaken only under the supervised care of a Health Care Provider.

Somryst delivers digital Cognitive Behavioral Therapy for Insomnia (CBT-I) therapeutic content. CBT-I is a neurobehavioral treatment that focuses on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate sleep problems, regardless of the original source of the sleep problem.

CBT-I is typically delivered by a specially-trained clinician, either 1:1 or in group format. Standard delivery of CBT-I usually occurs in weekly sessions over 6-8 weeks. CBT-I is a scientifically proven behavioral treatment.

How to Start Using Somryst:

The following steps will help guide the Health Care Provider's use of Somryst and the Clinician Dashboard correctly:

- Prescribing Somryst
  - A licensed clinician prescribes Somryst via the enrollment form, which can be submitted in one of three ways: 1) PearConnect HCP Portal; 2) Electronic prescription tool (eRx) from your EHR system; or 3) PDF enrollment form.

- Your patient will be contacted by PearConnect™ to obtain their consent and onboard them via text.
- Your patient will receive a prescription Access Code. To activate Somryst, your patient will need to launch the Somryst app after downloading it from the Apple App Store or the Google Play Store.
- Once your patient sets a password and pin, your patient can then begin working and learning with Somryst.

- Tracking patient progress on PearMD
  - After a patient starts Somryst, you will receive a message via email sent to the email address provided during the prescription process. The email contains a link to verify the account and set a password. Once an account is created, the Dashboard can be accessed at any time by visiting www.pear.md.
  - You can view your patient's progress, use of Somryst app, and view patient-reported data through the dashboard.

Please see full Clinician Directions for Use (DFU) in the clinician dashboard for complete instructions on how to use the Somryst Clinician Dashboard and how patients can share information with their clinician using Somryst.

What Operating Systems Does Somryst Support?

The Somryst app is supported on the following mobile operating systems:

- iOS 11 or higher
- Android 7 or higher

Please ensure your patient's smartphone or tablet is running an Operating System (OS) version matching those above. If not, then please instruct the patient to update their software version before downloading and using Somryst.

Additional Support Available:

For additional questions regarding the Somryst app, contact PearConnect™ via email at support@pearconnect.com or by phone at 1-833-697-3738.

Rx Only

Legal Manufacturer: Pear Therapeutics, Inc., 201 Mission St. #1450, San Francisco, CA 94150