

## 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 Somryst Clinician Directions for Use within the Somryst Clinician Dashboard for the complete Important Safety Information.**

#### Indications for Use

Somryst™ is a prescription-only digital therapeutic intended to provide a neurobehavioral intervention (Cognitive Behavioral Therapy for Insomnia – CBT-I) in 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 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 Cognitive Behavioral Therapy for Insomnia

#### Safety Information and Warnings

Somryst™ is not for everyone. Please use your clinical judgement 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 Provider.
- Somryst is not meant to be used as treatment without supervision of a Health Care Provider.

- Somryst is not meant to be a substitution for any treatment medication.
- Somryst contains sensitive medical information. Please instruct patients to protect their information by password-protecting their smartphone and 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 which 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 specialty-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 can be conceptualized as six sessions or Cores that deliver proven behavioral and cognitive treatment strategies. Somryst delivers treatment with the following 6 treatment Cores:

1. **Get Ready:** This Core sets the stage for the therapeutic experience. It lets patients know what they will need to learn and do to improve sleep.
2. **Sleep Window:** This Core is one of the most important ones. The patient will receive their first Sleep Window - a recommended Bedtime and Arising Time.
3. **Behaviors:** This Core helps patients identify and change certain habits and behaviors that can interfere with sleep. It establishes the key guidelines of CBT for insomnia.
4. **Thoughts:** This Core explains how a patient's thinking can contribute to insomnia. The patient will learn to identify and shift problematic thought patterns.
5. **Education:** This Core helps patients figure out what changes in their lifestyle and environment can promote better sleep.
6. **Looking Ahead:** This Core pulls together what patients have learned, prepares patients for the future, and teaches them what to do if they experience a relapse.

Somryst™ includes a daily Sleep Diary in which patients record information about their sleep. The My Stuff section provides selected resources and elements from each Core for review. The My Stuff section for each Core is available after the Core is completed.

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### Who Should Use Somryst™

Your patient should only use Somryst if they:

- Are 22 or older with chronic insomnia
- 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, i.e., have internet/wireless connection access
- Are under the supervision of a Health Care Provider

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### Benefits of Somryst™

Use of Somryst can result in significant and lasting improvements to insomnia symptoms for your patients.

Results from the Somryst Pivotal Studies showed patients experience a significant reduction in severity of insomnia after treatment, with more than 40% of the patient group no longer meeting the criteria for insomnia.

Therapeutic benefits from the use of Somryst is only possible for your patients if they follow the instructions and practice the exercises and strategies provided in the program. Treatment results may vary for your patients.

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

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### Security

Please remind patients that it is their responsibility to secure their mobile device (smartphone or tablet). If the patient uses an iPhone or iPad, they should use a 6-digit passcode known only to them. If available, Touch ID or Face ID should be used. If the patient uses an Android phone or tablet, they should use a password or 6-digit passcode and enable fingerprint-unlock if available.

It is the patient's responsibility to update their phone or tablet operating system when recommended by the platform vendor (Apple or Google). Important security updates are included in operating system upgrades. The vendor will do this by notifying the patient on their device that an update is available for download and install.

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### Additional Support

For additional support the patient can contact their Health Care Provider, or email Somryst support at [support\\_somryst@peartherapeutics.com](mailto:support_somryst@peartherapeutics.com).

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### Somryst™ Prescriptions

#### Dose and Frequency

Patients should be clearly instructed to complete a dose of all 6 treatment Cores. Patients who have completed all 6 Cores have shown the best outcomes.

Each core should be completed on a frequency of one core every 7 days.

Patients should complete their Sleep Diary daily and follow the sleep restriction window recommendations provided by Somryst.

#### Duration and Extension

Patient access to Somryst will automatically discontinue after 9 weeks (63 days). The prescription will end automatically based on the start date. Additional 9-week use of the therapy may benefit the patient, as insomnia is a chronic disease.

## Downloading Somryst

Your patients will have to download Somryst to access the product. Below are instructions needed to obtain access to Somryst:

To download Somryst on the **iPhone or iPad**:

- Tap the App Store icon on the home screen:
- Tap the search icon and type “Somryst.”
- Tap the “GET” button. The patient may need to enter their Apple ID and password or use Touch ID or Face ID to approve the download.
- When Somryst is downloading, the Somryst icon will be visible on the home screen. Download progress is indicated within the icon.
- Tap the Somryst icon to open the app when download completes.

To download Somryst on an **Android phone or tablet**:

- Tap on the Play Store app on the Android phone
- Tap on the search bar and type “Somryst”
- Tap "Install"
- Somryst will ask to access the calendar and other information – tap “Yes”
- When Somryst is downloaded, either tap "Open" in the Play Store
- Or, go to the home screen and tap the Somryst icon

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## Compatible Devices

Somryst™ is compatible with mobile devices (including smartphone and tablet) running:

- iOS version 9.0 or higher
- Android version 5.0 or higher

Please ensure your patient’s mobile device is running an Operating System (OS) version matching those above. If not, then please instruct the patient to take the time to update their software version before downloading and using Somryst



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