**PREVENT SLEEP APNEA THERAPY 30 NIGHT STATER KIT**

The 30 Night Starter Kit is an optional package designed to help you become accustomed to Prevent by gradually increasing resistance over three consecutive nights of therapy. It includes 2 High resistance, 2 Medium resistance, and 3 Standard resistance devices. When using the Prevent Regimen:

- **Use Light resistance Non-Therapeutic devices for nights 1 & 2.**
- **Use Medium resistance Non-Therapeutic devices for nights 3 & 4.**
- **Use Standard resistance Therapeutic devices for nights 5 & 6.**

**PREVENT SLEEP APNEA THERAPY 30 NIGHT STANDARD PACK**

The 30 Night Standard Pack is designed for experienced Prevent users and includes 30 Standard resistance Prevent Nasal Devices. (The 30 Night Standard Pack can be used with a different device to increase compliance; however, the first two nights of sleeping with Prevent Nasal Devices may be uncomfortable.)

**GETTING USED TO THE THERAPY**

It may take up to a week or longer to adjust to Prevent Sleep Apnea Therapy. In that time, the device may feel uncomfortable for the first few nights. Here are some guidelines to help you get used to Prevent Nasal Devices before and during your therapy:

- **Inflate** – Breathe out through the mouth in the morning before you wake up. This helps you get more acclimated to the device.
- **Exhale** – Breathe out through your mouth in the morning before you wake up. This helps you get more acclimated to the device.
- **Inhale** – Breathe in through your nose in the morning before you wake up. This helps you get more acclimated to the device.
- **Relax** – Avoid any restrictive activities while using the device. Ideally, you should put on Prevent Sleep Apnea Therapy before you go to sleep. Keep a glass of water nearby and be ready to take the device off if you have any discomfort.

**DIRECTIONS FOR USE**

**Familiarize yourself with the device components of the device.**

- **Peel off the adhesive from the paper backing.**
- **Align the long axis of the nasal insert with the long axis of your nostril to ensure a good seal.**
- **Observe** – The device should not be visible from the outside of the nostril. You should not feel it in your sinuses.
- **Listen** – You may hear the sound of air being forced into your nostrils and in your ears. This is normal and is believed to be helpful to acclimation.

**INDICATION**

Prevent Sleep Apnea Therapy is indicated for the treatment of obstructive sleep apnea (OSA).

**CONTRAINDICATIONS**

- **Respiratory distress or other conditions that may be exacerbated by therapies that increase upper airway resistance (e.g., nasopharyngeal occlusion by positive pressure).**
- **Obstructive sleep apnea or apnea-hypopnea index greater than 100.**
- **Patients with severe obesity and those with obesity hypoventilation syndrome.**
- **Central sleep apnea.**
- **Advanced cardiovascular disease or obesity hypoventilation syndrome.**
- **Increased intracranial pressure.**
- **Active upper respiratory infections (including nasal, sinus or middle ear) or infections or infestations, or participation in the device.**

**WARNINGS**

- **Adherence to instructions for use is required to make the therapy effective.**
- **Patients who experience an allergic reaction to any part of the device should discontinue use of the Prevent Nasal Device and consult a physician.**
- **Patients who are unable to breathe through their mouth or experience insufficiency in nasal breathing while using the device should discontinue use of the Prevent Nasal Device and consult a physician.**
- **Prevent should not be used in patients with hypersensitivity to the material. A clinical study has shown that therapy can result in a significant improvement in the quality of life.**
- **Patients who develop nasal, eye, or ear irritation or have conjunctivitis should discontinue use of the Prevent Nasal Device and consult a physician.**
- **Patients who experience severe nasal or eye irritation should discontinue use of the Prevent Nasal Device and consult a physician.**
- **Patients who develop pain in their ears or nose should consult a physician.**

**PRECAUTIONS**

- **Patients should be instructed to breathe through their mouth while using the device.**
- **The safety and effectiveness of Prevent in program studies are only slightly below the age of 18, and patients with cardiac or sleep apnea have not been established.**
- **Children should use one只为 Prevent Nasal Device for children that is not a sleep apnea device (e.g., overnight). The device is prescribed for single use only and should be disposed of after use.**
- **The Prevent Nasal Devices are made from silicon.**

**ADVERSE REACTIONS**

Patients treated with sleep apnea therapy may experience dry mouth, red, dry, or stuffy noses, or epistaxis. The device may be uncomfortable and cause discomfort in the nostrils, nose, mouth, or throat. The device may cause redness, swelling, and irritation of the device.

**HOW SUPPLIED**

The Prevent Nasal Device is supplied non-sterile and is intended for single use only. Each pack contains two nasal inserts (one Prevent Nasal Device) intended to be used together for one night’s therapy and not to be stored in a dry place.

**IMPORTANCE OF TREATMENT CONTINUITY**

OSA is a chronic disease that should be treated every night. If the patient experiences any continuation or recurrence of symptoms after starting Prevent therapy, the patient should consult their physician.