

Caution: In the US, federal law restricts this device to sale by or on the order of a physician.

Carefully read all labeling information prior to using this device.

Description

Provent® Sleep Apnea Therapy is a disposable nightly-use nasal device.

The Provent Nasal Device is placed just inside the nostrils and is held in place by adhesive. The device directs expiratory flow through small holes, which increases airway pressure during the expiratory phase of the respiratory cycle in similar fashion to the expiratory phase of CPAP therapy. This airway pressure is maintained until the start of the next inspiration. The expiratory resistance created by the Provent Nasal Device helps maintain an open airway during sleep. The Provent Nasal Device should be used only after consultation with a licensed healthcare professional.

Indication

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

Contraindications

Based on clinical studies involving similar therapies, Provent Sleep Apnea Therapy is contraindicated for use in patients with the following conditions:

- Severe breathing disorders including hypercapnic respiratory failure, respiratory muscle weakness, bullous lung disease (as seen in some types of emphysema), bypassed upper airway, pneumothorax, pneumo-mediastinum, etc.
- Severe heart disease (including heart failure).
- Pathologically low blood pressure.
- An acute upper respiratory (including nasal, sinus or middle ear) inflammation or infection, or perforation of the ear drum.

Warnings

- Assessment of effectiveness and follow-up testing and evaluation should be conducted to ensure adequate treatment effect.
- Patients who experience an allergic reaction to any part of the device should discontinue use of the Provent Nasal Device and consult a physician.
- Patients who are unable to breathe through their mouth or experience excessive discomfort when breathing through the device should discontinue use of the Provent Nasal Device and consult a physician.
- Provent should not be used in patients with hypercapnic respiratory failure. A clinical study has shown that Provent Therapy can result in a moderate but stable increase in Pco₂ in some users.

- Patients who develop nasal, sinus or ear infection or inflammation should discontinue use of the Provent Nasal Device and consult a physician.

- Patients who experience severe nose bleed should discontinue use of the Provent Nasal Device and consult a physician.

- Patients who develop skin or mucosal irritation, rash, sores, or other discomfort in or around the nose should discontinue use of the Provent Nasal Device and consult a physician.

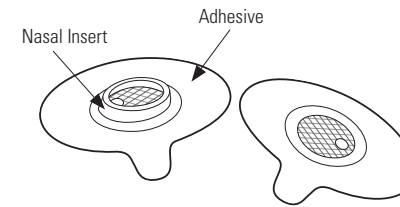
- Keep out of reach of children.

Precautions

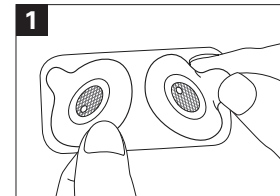
- Patients should be instructed to breathe through their mouth while falling asleep.
- The safety and effectiveness of Provent Therapy in pregnant women, children under the age of 18, and patients with central sleep apnea have not been established.
- Patients should not use any single Provent Nasal Device for longer than one sleep cycle (e.g., overnight). The Provent Nasal Device is intended for single use only and should be disposed of after use.
- Reuse of the Provent Nasal Device will weaken the adhesive, resulting in an inadequate seal and reduced effectiveness of the device.
- Patients should not use the Provent Nasal Device if they have any sores, abrasions, or skin or mucosal irritation on or around the nose.

Adverse Reactions

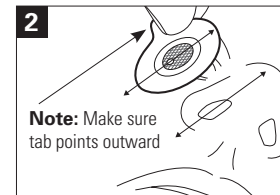
Potential adverse reactions include dry mouth/throat/lips; nasal congestion/runny nose; nasal, sinus, throat, ear, or breathing discomfort; headache; allergic reaction; skin irritation/discomfort; difficulty falling/staying asleep; vertigo; anxiety and nose bleed.



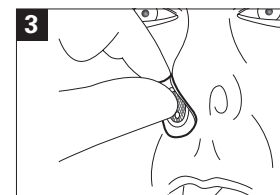
Directions For Use



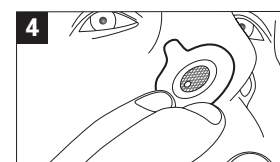
1 Peel off the adhesive from the paper backing.



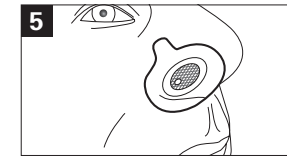
2 Align the long axis of nasal insert with the long axis of one of the nostrils to ensure a good seal. Make sure the side tab points outward.



3 Once aligned, place the nasal insert into the nostril. Stretch the lower nostril area as if shaving the area above the upper lip. This will help ensure a good seal.



4 Gently press down around the adhesive to ensure a good seal. Check to make sure there are no folds or creases which may compromise the seal.



5 Once in place, the adhesive should be adhered as shown. Repeat steps 1-4 for the other nostril.

Use a mirror to check that both devices are properly fitted. Some overlap of the adhesive portions of the two devices is common, but make sure the adhesive does not cover the plastic mesh of the other device.

Run your fingers around the edges of the devices to ensure a good seal. Check that there are no air leaks in the area between the upper lip and lower, outer nostril.

If you find that one of the devices is not positioned correctly, remove the device and try repositioning it.

Repeated repositioning of the device will weaken the adhesive and reduce the effectiveness of the device. If the adhesive no longer feels sticky, dispose of the device and apply a new one.

Breathe in and out through the mouth while falling asleep or in through the nose and out through the mouth - whichever is more comfortable.

Remove the Provent Nasal Device by gently peeling the adhesive away from the nostril and discard.

How Supplied

The Provent Nasal Device is supplied non-sterile and is intended for single use only. Each pouch contains two valves (one Provent Device) intended to be used together for one night's use and should be stored in a cool, dry place.

Importance of Treatment Continuity

OSA is a chronic disease that should be treated every night during sleep. If the patient experiences any continuation or recurrence of symptoms of OSA after using Provent Sleep Apnea Therapy, the patient should consult his or her physician.

Directions for Wearing Provent Therapy:

Provent Therapy may take some "getting used to". The device works by making it harder to breathe out through your nose, which helps create the pressure needed to treat your obstructive sleep apnea. It should require up to a week of use or longer to feel comfortable breathing with the device. These tips will help you get used to wearing the Provent Device before and during sleep.

1. INHALE

- Inhale through your mouth or through the device - whichever is more comfortable for you to fall asleep.

2. EXHALE

- Breathe out through your mouth while awake and trying to fall asleep.
- If you try breathing through your nose (to check the seal of the adhesive, for example) notice the significant resistance. This is normal and tells you the device is working.
- Generally, people switch to nasal breathing once asleep, effectively "turning on" the device.

3. RELAX

- Simply apply the device and go to bed.
- Do not engage in any activity while wearing the device—just try to fall asleep.
- Keep a glass of water near your bedside, in case you wake up with a dry mouth.

4. REPEAT

- If you wake up feeling uncomfortable, just take it off and try again tomorrow.
- Take time to get used to wearing Provent Therapy.

5. COMMIT

- Use all devices provided in the pack.
- The first few nights may be uncomfortable, but you should get used to it.



Barber D.M.E. Supply Group

4080 Lafayette Center Drive, Suite 250
Chantilly, VA 20151 USA

For customer service inquiries or to report an adverse event, please call:
+1 (703) 378-4353, or send an email to: info@sleepwellrested.com.

Product Identifiers:

Provent Sleep Apnea Therapy: 08592-0002-30