

PROVENT[®]

sleep apnea therapy

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.

PROVENT SLEEP APNEA THERAPY 30-NIGHT STARTER KIT

The 30-Night Starter Kit is an optional package designed to help new users become acclimated to Provent by gradually increasing resistance over the first several nights of therapy. It includes 2 Light resistance, 2 Medium resistance, and 26 Standard resistance devices. When using the Provent Starter Kit:

- 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 5-30

PROVENT SLEEP APNEA THERAPY 30-NIGHT STANDARD PACK

The 30-Night Standard Pack is designed for experienced Provent users and includes 30 Standard resistance Provent Nasal Devices. (The 30-Night Standard Pack can be used by first time Provent users; however the first few nights of sleeping with Provent may feel uncomfortable.)

GETTING USED TO PROVENT THERAPY

It may take up to a week or longer to adjust to Provent Sleep Apnea Therapy. In fact, wearing the device may feel uncomfortable for the first few nights. These tips will help you get used to wearing the Provent Nasal Device before and during sleep:

INHALE - Inhale through your mouth or through the Provent Nasal Device – whichever makes it more comfortable to fall asleep.

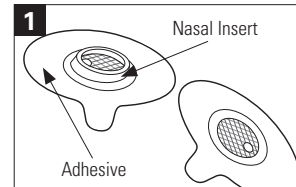
EXHALE - Breathe out through your mouth (not through the device) when awake. If you try breathing through your nose (to check the seal of the adhesive, for example) you should notice resistance. This is normal and tells you the device is working. While you are trying to fall asleep, breathing out through your mouth will feel a lot more comfortable. Generally, people switch to nasal breathing once asleep, effectively “turning on” the device.

RELAX - Avoid or minimize activity while wearing the device. Ideally, you should put on Provent right before you’re about to go to sleep. Keep a glass of water near your bedside, in case you wake up with a dry mouth.

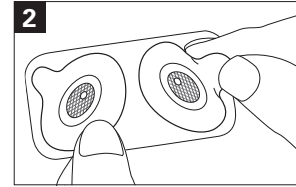
REPEAT - If you wake up feeling uncomfortable during the night, take the device off and try again tomorrow. Some people adjust to Provent Therapy right away; others need more time. It may take a week or more to get used to sleeping with the device. Give it the time you need.

COMMIT - Use all devices provided in the pack. Remember, sleep apnea is a lifelong medical condition that should be treated. Although it may take time to get used to wearing Provent Therapy, consider the positive benefits of treatment.

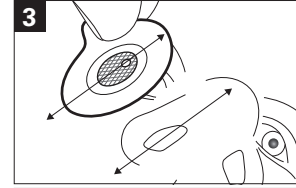
DIRECTIONS FOR USE



Familiarize yourself with the different components of the device.

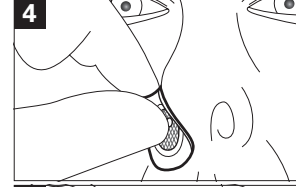


Peel off the adhesive from the paper backing.



Align the long axis of the nasal insert with the long axis of your nostril to ensure a good seal.

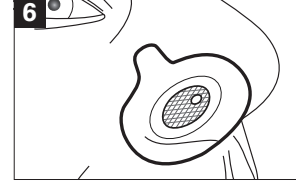
Note: Make sure the side tab points outward.



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.



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.



Once in place, the adhesive should be adhered as shown. Repeat steps 2-5 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 of one device does not cover the plastic mesh of the other.
- 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.
- As with nasal CPAP therapy, Provent Therapy users who may be mouth breathing during sleep may benefit from the use of a chinstrap.
- After use remove the devices, by gently peeling the adhesive away from the nostrils, and discard.

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, pneumomediastinum, 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 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.

How Supplied

The Provent Nasal Device is supplied non-sterile and is intended for single use only. Each pouch contains two valves (one Provent Nasal 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.

PHYSICIAN INFORMATION

Clinical Data

Below is a summary of the clinical trial data of Provent Sleep Apnea Therapy including pooled data of different expiratory resistances which have been determined to have equivalent clinical effects.

Objective of the Studies

The objective of the studies was to evaluate the effectiveness of Provent Sleep Apnea Therapy in treating obstructive sleep apnea (OSA).

Test Methods, Procedures and Conditions

In multicenter, prospective trials, subjects underwent polysomnographic (PSG) evaluations, some with the device in place (treatment) and some without (control). To address the “first night effect,” the treatment/control night order was randomized. PSG data were scored by an independent certified sleep technologist who was blinded to subject and device/control status.

Study Measures

The Apnea-Hypopnea Index (AHI), Apnea Index (AI), duration of apneas, Oxygen Desaturation Index (ODI), total sleep time (TST), and sleep efficiency were compared and contrasted between control and treatment nights. Sleep parameters were scored either using the Chicago Criteria¹ or the AASM recommended criteria² with the control and treatment night for each patient scored using the same criteria.

Study Results

The AHI, AI and ODI were significantly improved ($p \leq 0.001$) in the treatment nights as compared to control nights (see Table 1). Total sleep time, sleep efficiency and duration of apneas were not significantly different, indicating that the Provent Nasal Device did not worsen sleep parameters and did not extend apnea duration. Further results of four effectiveness studies are stratified by control night OSA severity and presented in Tables 2, 3 and 4.

Table 1: Analysis of Apnea-Hypopnea Index, Apnea Index and Oxygen Desaturation Index
(Subjects with Control Night AHI ≥ 5)

	N	Mean	Median	Min to Max	STD	p-value*
Apnea-Hypopnea Index (apneas and hypopneas per hour of TST)						
Control Night	191	27.4	18.2	5.1 to 118.7	23.6	
Treatment Night	191	15.5	8.2	0 to 114.1	20.05	
Treatment - Control	191	-11.9	-9.5	-59.35 to 41.54	13.9	<0.001
Apnea Index (apneas per hour of TST)						
Control Night	191	18.5	12.0	0 to 104.7	20.4	
Treatment Night	191	8.7	3.0	0 to 84.8	14.9	
Treatment - Control	191	-10.0	-7.2	-65.2 to 18.9	13.8	<0.001
Oxygen Desaturation Index (3% desaturations per hour of TST)						
Control Night	191	21.4	13.4	0.1 to 110.3	21.9	
Treatment Night	191	14.1	7.3	0 to 103.8	18.2	
Treatment - Control	191	-7.3	-4.5	-58.3 to 51.6	12.6	<0.001

Note: *p-value from a paired t-test.

Table 2: Analysis of Apnea-Hypopnea Index by OSA Severity

	N	Mean	Median	Min to Max	STD	95% CI
Mild OSA (control night 5<AHI≤15)						
Control Night	67	9.6	9.3	5.1 to 14.9	3.2	
Treatment Night	67	6.5	5.2	0.15 to 48.5	7.2	
Treatment - Control	67	-3.1	-4.3	-12.91 to 41.54	7.3	(-4.9, -1.4)
Moderate OSA (control night 15<AHI≤30)						
Control Night	68	20.7	19.7	15.0 to 29.6	4.6	
Treatment Night	68	10.0	7.9	0 to 38.8	8.1	
Treatment - Control	68	-10.7	-11.9	-24.7 to 19.0	8.8	(-12.8, -8.6)
Severe OSA (control night AHI>30)						
Control Night	56	57.0	50.2	30.0 to 118.7	23.5	
Treatment Night	56	33.0	26.1	1.1 to 114.1	28.0	
Treatment - Control	56	-24.0	-25.1	-59.4 to 6.4	16.1	(-28.2, -19.7)

Table 3: Analysis of Apnea Index by OSA Severity

	N	Mean	Median	Min to Max	STD	95% CI
Mild OSA (control night 5<AHI≤15)						
Control Night	67	4.9	4.6	0 to 13.8	3.6	
Treatment Night	67	3.1	1.5	0 to 21.2	4.4	
Treatment - Control	67	-1.8	-2.0	-10.9 to 16.5	5.0	(-3.0, -0.6)
Moderate OSA (control night 15<AHI≤30)						
Control Night	68	13.3	13.5	0 to 28.0	6.7	
Treatment Night	68	5.9	2.6	0 to 38.0	7.5	
Treatment - Control	68	-8.3	-9.1	-59.4 to 18.9	10.6	(-10.8, -5.8)
Severe OSA (control night AHI>30)						
Control Night	56	41.0	32.6	8.0 to 104.7	24.5	
Treatment Night	56	19.0	10.4	0 to 84.8	22.9	
Treatment - Control	56	-21.9	-21.2	-65.2 to 11.4	16.1	(-26.1, -17.7)

Table 4: Analysis of Oxygen Desaturation Index (3% Desats/Hour) by OSA Severity

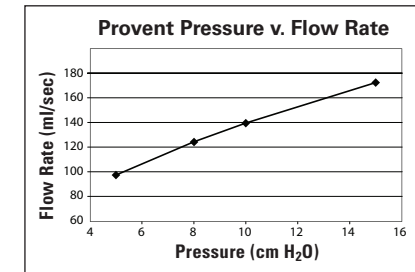
	N	Mean	Median	Min to Max	STD	95% CI
Mild OSA (control night 5<AHI≤15)						
Control Night	67	7.1	6.7	0.2 to 27.5	5.1	
Treatment Night	67	5.8	4.0	0 to 58.5	7.8	
Treatment - Control	67	-1.3	-1.6	-17.0 to 51.6	8.0	(-3.2, 0.6)
Moderate OSA (control night 15<AHI≤30)						
Control Night	68	16.4	13.7	0.1 to 83.9	12.1	
Treatment Night	68	10.3	7.3	0.3 to 57.0	9.2	
Treatment - Control	68	-6.1	-5.4	-58.3 to 20.6	11.4	(-8.8, -3.4)
Severe OSA (control night AHI>30)						
Control Night	56	44.5	37.9	3.6 to 110.3	25.2	
Treatment Night	56	28.5	21.1	0.5 to 103.8	25.6	
Treatment - Control	56	-15.9	-15.4	-48.2 to 12.3	14.0	(-19.6, -12.3)

No device-related serious adverse events were reported during the studies.

Note: Tables 1-4 include pooled data from Ventus Medical clinical studies (C001, C005, C009, C020).

¹American Academy of Sleep Medicine Task Force, “Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research,” SLEEP, Vol. 22, No. 5, 1999: 667-689.

²Iber C, Ancoli-Israel S, Chesson A, Quan SF for American Academy of Sleep Medicine. The AASM manual for scoring of sleep and associated events: rules, terminology and technical specifications, 1st ed. Westchester, IL: American Academy of Sleep Medicine, 2007.



DESCRIPTION OF SYMBOLS

	Catalogue Number		Use By Date
	Batch Code		Do Not Reuse
	Manufacturer		Consult Instructions For Use
	Authorized Representative		CE Mark
	Keep Dry		Prescription

USER ASSISTANCE INFORMATION



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For customer service inquiries or to report an adverse event, please call:
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Product Identifiers:

Provent Sleep Apnea Therapy Standard Pack: 08592-0002-30
Provent Sleep Apnea Therapy Starter Kit: 08592-0003-26



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