

The VNS Therapy[®] Magnet

A unique benefit of VNS Therapy



To Learn More

call 1-888-867-7846

or visit VNSTherapy.com

Rosario
on VNS Therapy
since 2016



What is the VNS Therapy® Magnet?

VNS Therapy automatically delivers therapy at regular intervals throughout the day in an effort to control your seizures. The magnet is an optional benefit that may provide additional seizure control.



Standard Mode
Prevention Delivery



Detect & Respond
Responsive Delivery



Magnet Mode
On-Demand Delivery

The VNS Therapy magnet serves two functions

Provide an extra dose of therapy on demand.

If you experience a breakthrough seizure, this may:

- Stop the seizure
- Shorten the seizure
- Decrease the intensity of the seizure
- Improve the recovery period following the seizure

Temporarily suspend therapy to manage side effects during activities such as singing, public speaking or exercising.

How to use the VNS Therapy Magnet

Patients, family members, caregivers, teachers, and school nurses can use the magnet to initiate an extra dose of stimulation when the patient feels a seizure is about to start or during a seizure.



1 Respond

Always carry the magnet with you so you are ready to respond.



2 Pass (move)

Pass (move) the magnet over the generator for **less than** two seconds.

Two magnets are provided along with a wristband and a belt clip. When worn with the wristband, the magnet should be on the inside of your wrist.

The magnet can be used more than once during a seizure. Using the magnet more than once will not harm you or the generator.

When you want to control side effects by temporarily stopping stimulation, hold or tape the magnet over the generator. When the magnet is removed, stimulation will restart.

If you experience troublesome or painful side effects from VNS Therapy for an extended period of time, contact your physician.

Carry your magnet with you so that it is available for use as soon as a seizure occurs or to temporarily suspend therapy for side effect management



Tips on handling the VNS Therapy[®] Magnet

- Keep the magnet at least 25cm (10 inches) away from credit cards, televisions, computers, microwave ovens, or other magnets
- Do not drop the magnet; it can break if it falls on a hard surface
- The VNS Therapy magnet is the only magnet that should be used with the VNS Therapy system
- Contact your physician to get additional magnets

INTENDED USE / INDICATIONS --UNITED STATES

Epilepsy -- The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.

CONTRAINDICATIONS

The VNS Therapy System should not be used in people who have had the left vagus nerve cut (a left vagotomy). Anyone implanted with the VNS Therapy system CANNOT have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy. Injury or damage can occur during diathermy treatment whether the VNS Therapy system is turned "ON" or "OFF."

Note: Diagnostic ultrasound is not included in this contraindication.

WARNINGS

VNS Therapy carries some risks. Physicians should inform patients about the warnings, precautions, side effects, and hazards associated with VNS Therapy, including information that VNS Therapy may not be a cure for epilepsy. Since seizures may occur unexpectedly, patients should consult with a physician before engaging in unsupervised activities, such as driving, swimming, and bathing, or in strenuous sports that could harm them or others. The safety and efficacy of VNS Therapy has not been established for uses outside of its approved indications. A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. Patients should use the magnet to stop stimulation if they suspect a malfunction, and contact their physician immediately for further evaluation. Removal or replacement of the VNS Therapy system requires an additional surgical procedure.

Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition. VNS Therapy may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder. MRI can be safely performed provided specific guidelines are followed. Patients should contact their physician before scheduling an MRI.

Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias.

(AspireSR® and SenTiva® only) Physicians should be informed of any existing heart condition or active treatment for a heart condition (such as beta adrenergic blocker medications). The physician will determine if the Automatic Stimulation feature (also known as AutoStim and Detect & Respond) is appropriate for each patient.

PRECAUTIONS

The safety and efficacy of VNS Therapy has not been established for use during pregnancy. Patients who smoke may have an increased risk of laryngeal irritation. There is a risk of infection with the implantation surgery that may require the use of antibiotics to treat or removal of the device. The VNS Therapy system may affect the operation of other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable devices, careful programming of each system may be necessary to optimize the patient's benefit from each device.

(AspireSR® and SenTiva® only) Situations, including but not limited to exercise or physical activity, that cause rapid increases in heart rate may trigger AutoStim if the feature is ON. If this is a concern, patients can talk to their physician about ways to stop stimulation during these situations. Use of the AutoStim Mode (Detect & Respond feature) will result in reduced battery life, which may require more frequent generator replacements.

(SenTiva® only) Optional time-based features do not automatically adjust for Daylight Savings Time or differing time zones.

ADVERSE EVENTS

The most commonly reported side effects are hoarseness, sore throat, shortness of breath, and coughing. Other adverse events reported during clinical studies as statistically significant are ataxia (loss of the ability to coordinate muscular movement); dyspepsia (indigestion); hypoesthesia (impaired sense of touch); insomnia (inability to sleep); laryngismus (throat, larynx spasms); nausea; pain; prickling of the skin (paresthesia); pharyngitis (inflammation of the pharynx, throat); and vomiting. These typically occur only during stimulation, are well tolerated and noticed less as time goes on.

The most commonly reported side effect from the implant procedure is infection.

*THE INFORMATION CONTAINED IN THIS SUMMARY REPRESENTS PARTIAL EXCERPTS OF IMPORTANT PRESCRIBING INFORMATION TAKEN FROM THE PRODUCT LABELING. THE INFORMATION IS NOT INTENDED TO SERVE AS A SUBSTITUTE FOR A COMPLETE AND THOROUGH UNDERSTANDING OF THE VNS THERAPY SYSTEM NOR DOES THIS INFORMATION REPRESENT FULL DISCLOSURE OF ALL PERTINENT INFORMATION CONCERNING THE USE OF THIS PRODUCT. PATIENTS SHOULD DISCUSS THE RISKS AND BENEFITS OF VNS THERAPY WITH THEIR HEALTHCARE PROVIDER. PRESCRIPTION ONLY - DEVICE RESTRICTED TO USE BY OR ON THE ORDER OF A PHYSICIAN.

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Health innovation that matters

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