

VNS Therapy[®] for paediatrics



The first choice add-on in
drug-resistant epilepsy

Drug-resistant epilepsy in children:

A complex disease needs a comprehensive approach

VNS Therapy®:

- Can be used in combination with other approved treatments at any time
- Helps you to meet therapy goals and restore patient wellness

Reduced seizure frequency

frequency

Improved comorbidities

- Mood
- Alertness/Energy
- Cognition

Minimal side effects from treatment

consequences

patient wellness

severity

Reduced seizure severity

duration

Reduced seizure duration

Shortened post-ictal recovery period

Cyberonics, Inc.
Houston, Tex

VNS Therapy for paediatrics

Early intervention helps create brighter futures

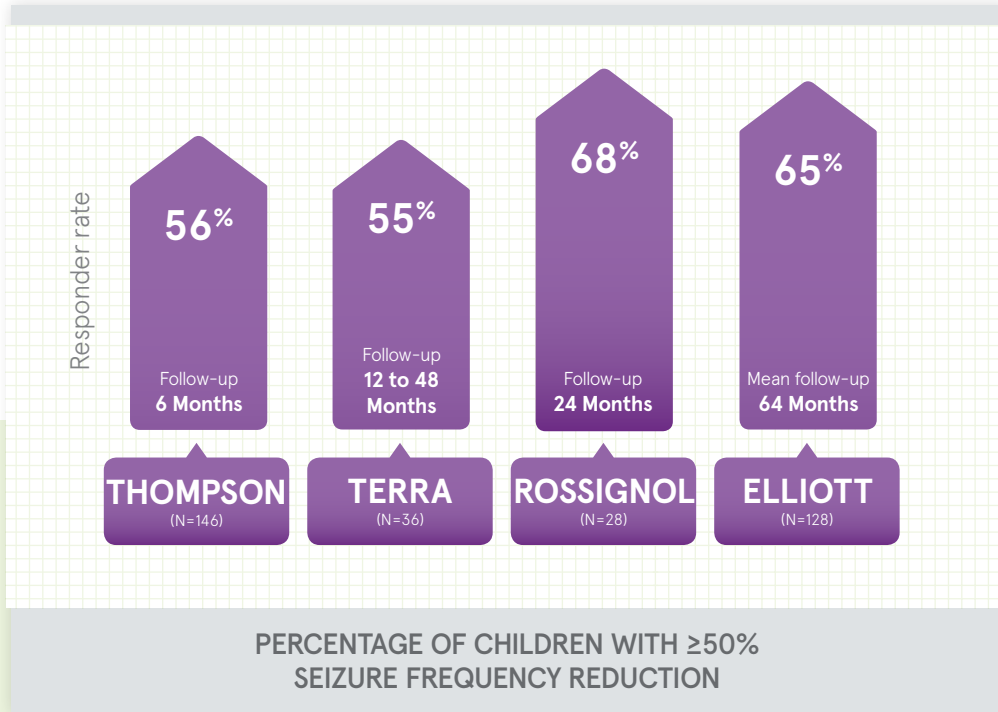
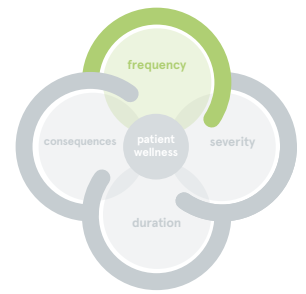
Effectiveness that improves and is maintained over time

- Multiple studies confirm VNS Therapy® effectiveness in children
- Children experience favourable reductions in seizure severity and duration
- Significant improvements in the Quality of Life (QoL) have been demonstrated in children

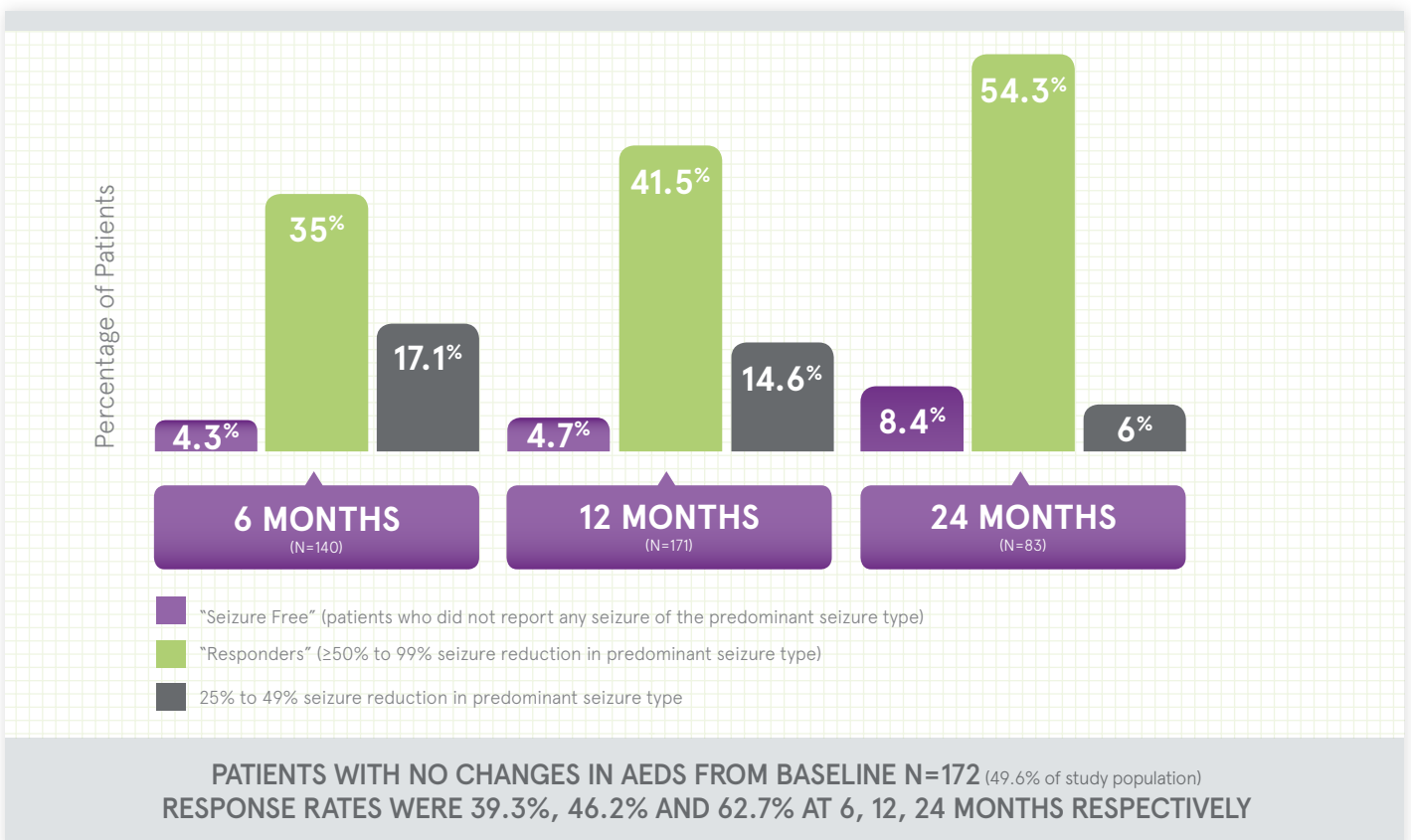


Multiple studies confirm VNS Therapy effectiveness in children

Long-term effectiveness of VNS Therapy confirmed across multiple studies²⁻⁵

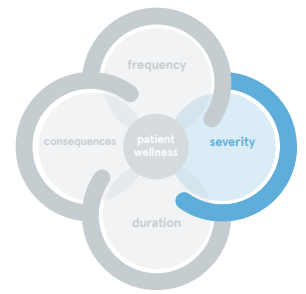


Changes in frequency of predominant seizure type^{*,1}

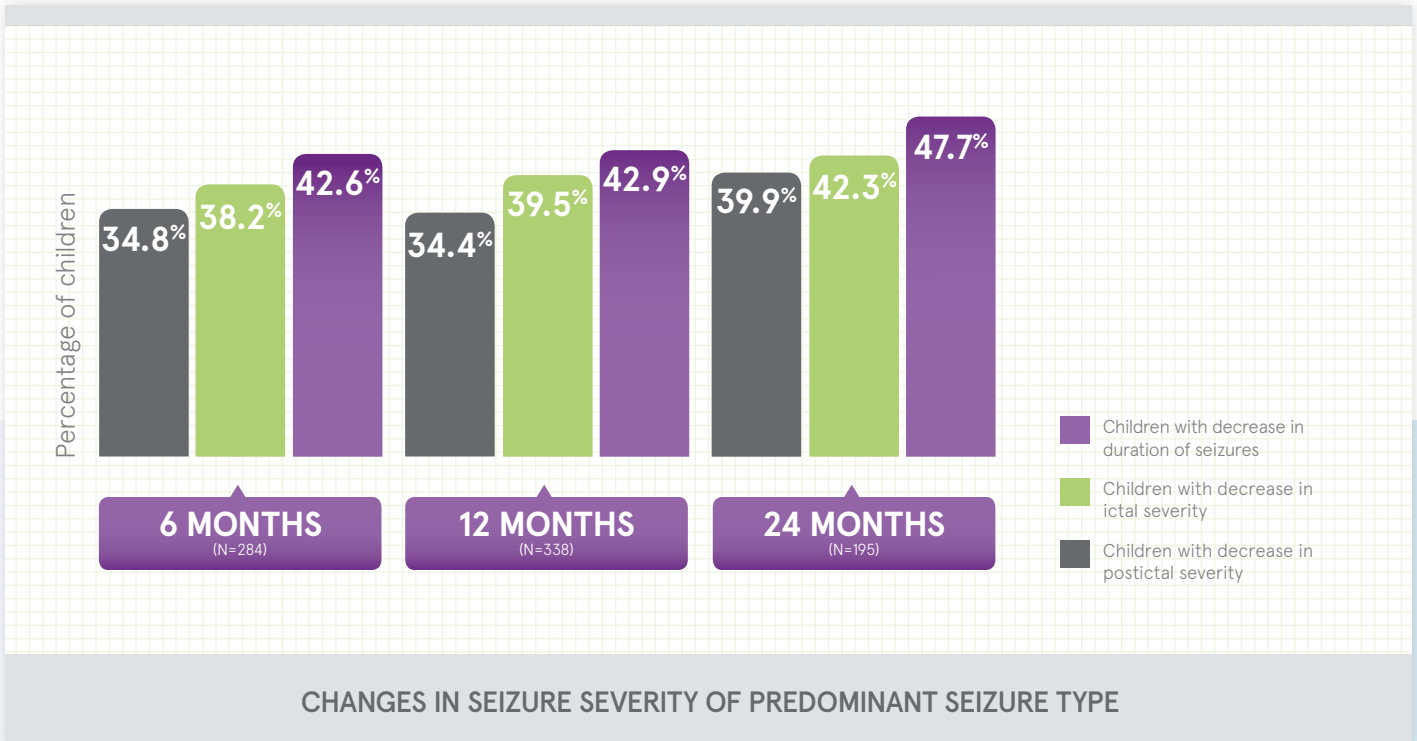


* Most disabling seizure type determined by the physician

Children experience favourable reductions in seizure severity and duration



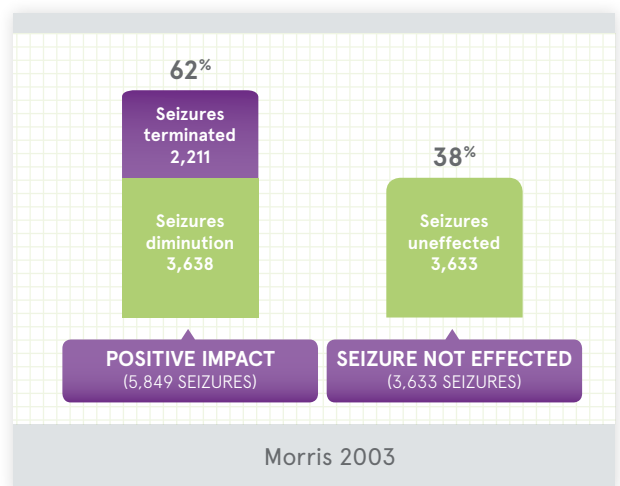
VNS Therapy has demonstrated long-term reductions in seizure severity and duration¹



Handheld magnet gives patients added control over seizures⁶⁻⁹

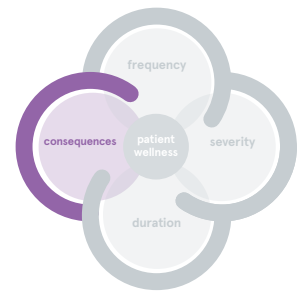
- On-demand stimulation can help increase patient confidence
- The handheld magnet may help shorten or stop a seizure, or improve postictal recovery

Effects in 9,482 seizures



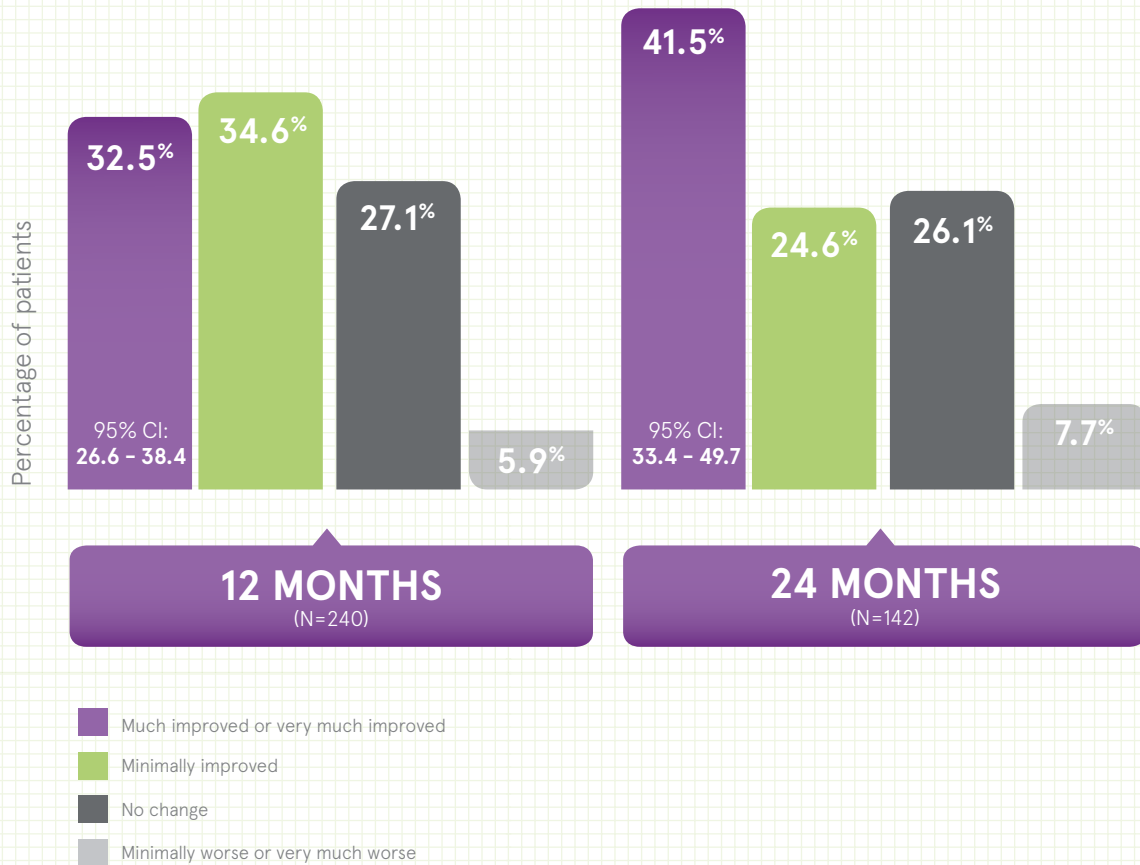
With AspireSR[®] patients can benefit from the extra Autostim feature that delivers automatic stimulation at the onset of a seizure. This may help to abort or shorten a seizure and reduce seizure severity.¹⁰

Significant improvements in Quality of Life (QoL) have been demonstrated in children



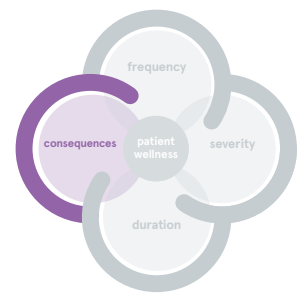
VNS Therapy has shown long-term Quality of Life benefits

About one-third of children show a much improved or very much improved QoL at 12 months with the proportion increasing at 24 months¹

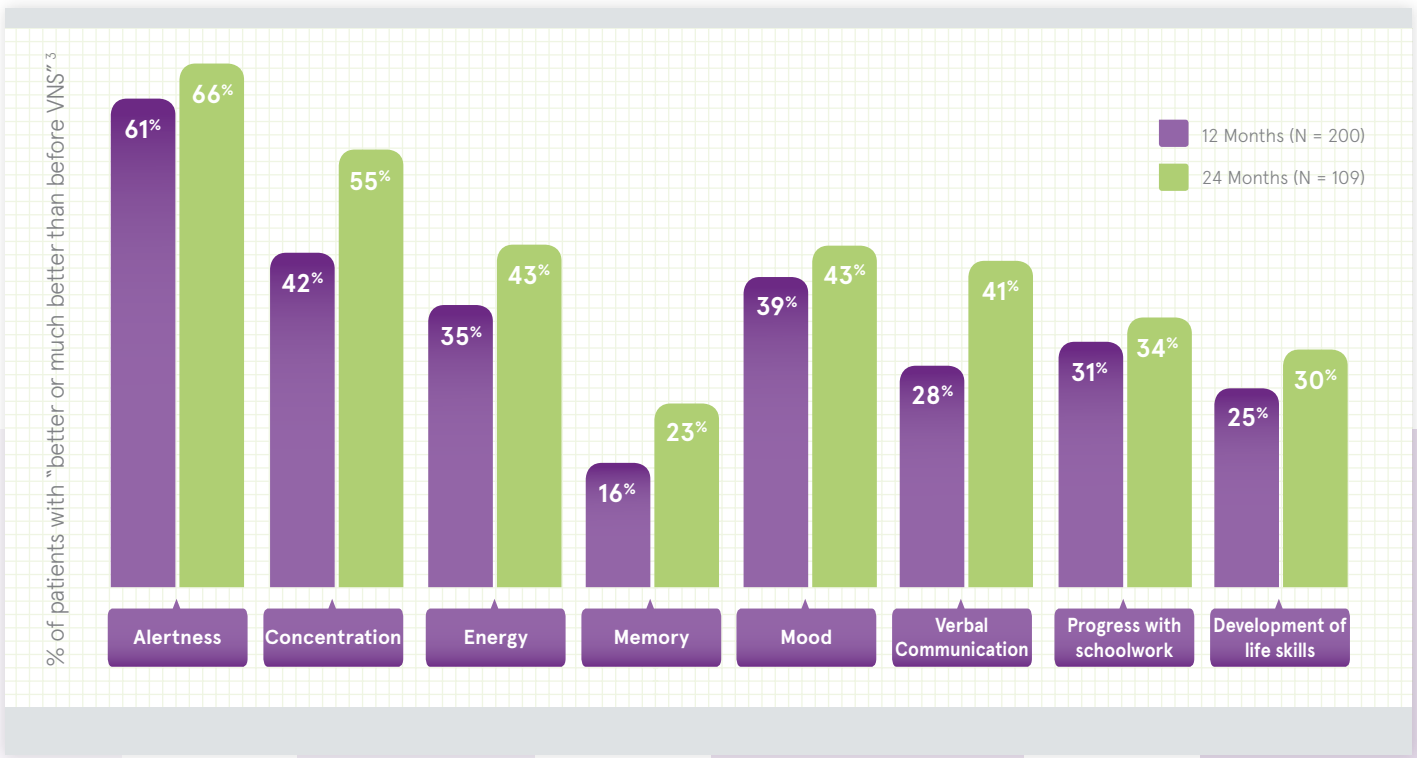


CLINICAL GLOBAL IMPRESSION OF IMPROVEMENT (CGI-I) ASSESSMENT



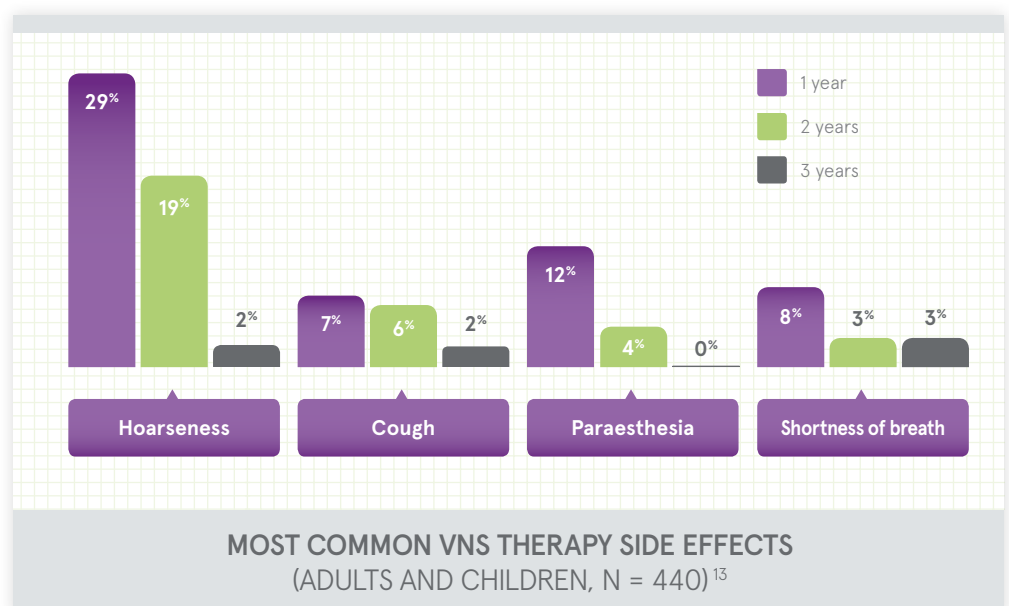


Quality of Life assessment parameters ¹



Common side effects related to VNS Therapy generally diminish over time

- Occur only during stimulation and generally diminish over time ¹¹⁻¹³
- May be diminished or eliminated by the adjustment of parameter settings ¹²
- Similar across age groups ^{14,15}





VNS Therapy® A foundational treatment that improves seizure control without adding pharmacological burden

- **VNS Therapy** is a non-drug adjunctive treatment that complements other treatment options. No brain surgery is required; implanting a VNS Therapy device is a minimally invasive procedure
- **Building compliance** VNS Therapy is automatically delivered at regular intervals all day, every day
- **Target dosing for maximum effectiveness** The generator allows you to customize and “titrate” the dose of stimulation to meet the individual needs of the patient

AspireSR® is CE mark approved and commercial distribution may vary by country.

VNS THERAPY EUROPEAN INDICATION FOR USE

VNS Therapy is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalization) or generalized seizures that are refractory to seizure medications. The Model 106 AspireSR® (Seizure Response) features the Automatic Stimulation Mode, which is intended for patients who experience seizures that are associated with cardiac rhythm increases known as ictal tachycardia.

CONTRAINDICATIONS:

The VNS Therapy system cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy system. Diagnostic ultrasound is not included in this contraindication. Cardiac arrhythmia (Model 106 only)—The AutoStim Mode feature should not be used in patients with clinically meaning arrhythmias or who are using treatments that interfere with normal intrinsic heart rate responses.

WARNINGS:

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy Physician Manuals, 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. A malfunction of the VNS Therapy system could cause painful or direct current stimulation, which could result in nerve damage. 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. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. MRI can be safely performed; however, special equipment and procedures must be used.

ADVERSE EVENTS:

The most commonly reported side effects from stimulation include hoarseness (voice alteration), paresthesia (prickling feeling in the skin), dyspnea (shortness of breath), sore throat and increased coughing. The most commonly reported side effect from the implant procedure is infection.

*The information contained here represents partial excerpts of important prescribing information from the product labeling. Patients should discuss the risks and benefits of VNS Therapy with their healthcare provider. Visit www.VNSTherapy.com for more information.

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References:

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CYBERONICS EUROPE BVBA
SUBSIDIARY OF LIVANOVA PLC

Airport Plaza
Kyoto Building
Leonardo Da Vincilaan 19
B-1831 Diegem, Belgium
Tel: +32.2.720.95.93
Fax: +32.2.720.60.53

100 Cyberonics Boulevard
Houston, Texas 77058
Tel: +1.800.332.1375
Fax: +1.281.218.9332
www.livanova.com