Available by prescription only

SHHHH—Treatment for ADHD in progress

Monarch eTNS® System

by NeuroSigma

external Trigeminal Nerve Stimulation for Attention Deficit Hyperactivity Disorder

Learn more at **www.monarch-etns.com**

Introducing a safe and effective non-medication treatment for children ages 7 to 12 years with ADHD

Millions of children are affected by Attention Deficit Hyperactivity Disorder (ADHD), a well-known neurological condition. Because the brains of children with ADHD are structured differently, they may be hyperactive and excitable, and have trouble regulating attention and controlling impulses. Such behavior can take an emotional toll on both children and their families.

Medication is the most common treatment for ADHD, but not everyone is comfortable with that choice. Also, some children don't respond well to medication, or develop side effects that limits their use. **Now you have another option:** an at-home treatment called the Monarch eTNS® System ("eTNS" stands for external trigeminal nerve stimulation).

Designed for bedtime use overnight

The Monarch eTNS® System is an FDA-cleared, at-home treatment for children ages 7 to 12 years old who are not currently taking prescription medication for ADHD. The system is designed for daily overnight use at home, and the therapy is based on government-funded scientific research. This non-invasive treatment has been proven effective in helping to relieve symptoms of ADHD, with very few side effects, and few long-term risks, and it works without the need for medication.

Indications and Important Safety Information

The Monarch external Trigeminal Nerve Stimulation (eTNS) System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep.

Contraindications: The Monarch eTNS System should not be used by patients with implanted cardiac and/or neurostimulation systems, or an implanted metallic or electronic device in their head. Please refer to the instructions for use for the full list of contraindications, warnings, precautions and other safety information, which is available at **www. monarch-eTNS.com/safety**.

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A non-medication treatment option for children with ADHD

About the size of a cell phone, the Monarch eTNS device connects to a disposable patch affixed on your child's forehead at bedtime. Once turned on, the device sends low stimulating pulses to the trigeminal nerve through the patch overnight.

How the Monarch eTNS System works to improve ADHD symptoms

- Treatment for ADHD is designed to help refocus the brain, much like glasses are used to help near-sighted children see better. The Monarch eTNS System helps to regulate the brain areas linked to ADHD symptoms via the trigeminal nerve, the largest nerve in the brain.
- The trigeminal nerve has branches that end close to the skin's surface just above the eyebrows. This nerve is a major pathway to a key brain region associated with attention, mood, and self-control, the prefrontal cortex (PFC).
- By using mild stimulating pulses delivered to the nerve through the skin, the Monarch eTNS System increases activity in the PFC, and decreases excitability in that brain area. Brain imaging studies have documented these effects.
- **The Monarch eTNS System is convenient and easy to use.** Just smooth the disposable patch onto the child's forehead at bedtime. Turn on and adjust the device for overnight treatment. The pulsing effects are mild and not intrusive. Children have described the stimulation as a tingling sensation on the skin. The treatment works while your child is sleeping. In the morning, remove the patch when the child wakes up.

Important Safety Information (continued)

Warnings: Children 7 to 12 years receiving eTNS treatment should be closely supervised by an adult who has read the user manual and is familiar with the Monarch eTNS System.

The Monarch eTNS System should:

- Only be used by the individual for whom it is intended
- Only be used with the guidance of a licensed physician
- Be used with caution in patients with heart disease or serious medical disorders
- Be kept out of the reach of infants and children under the age of 7 years
- Be used only as directed and be applied to healthy, clean, intact skin
- Not be used with other electronic therapeutic devices
- Not be applied on the neck or chest
- Not be used in the presence of electric monitoring equipment (e.g. cardiac monitors)
- Not be used in the bath or shower
- Not be used while operating machinery

The Monarch electric patches should not be used in patients with dermatitis or sensitive skin, as they are at higher risk of developing irritation, or be removed carelessly as this may damage the skin.

The Monarch lead wires should not be allowed to wrap around the neck.

Do not attach the electric patches:

- Anywhere on the body other than the forehead
- On the neck
- On the chest
- Over a defect in the skull (i.e. post brain surgery)

What to expect from eTNS treatment:

Full effects usually seen within 4 weeks

Device performance was established in two clinical trials. Trials suggest that a response to eTNS may take up to 4 weeks to become noticeable.

The effectiveness and tolerability of this device was first seen in an 8-week study of 24 children aged 7-14 years being treated for ADHD. This trial showed a 47% decrease in the ADHD Rating Scale IV (ADHD-RS-IV) score, and a responder rate of 71% on the Clinical Global Impressions Scale-Improvement (CGI-I) rating after 8 weeks.

After 4 weeks of nightly use:

64% of the children were rated as "improved" or "improved very much" on a parent-completed rating scale

After 8 weeks of nightly use:

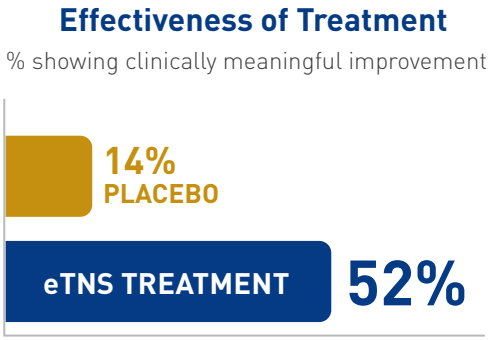
71% were rated as "improved" or "improved very much"

Everyone used the treatment as directed, side effects were minimal, and no child withdrew from the study due to adverse events.

Based on these positive results, the treatment was studied in another 4-week controlled study. Children with ADHD ages 8-12 years were randomly assigned to active treatment or sham-controlled (placebo) treatment (sham-controlled treatment means that the device used didn't provide nerve stimulation).

Symptom improvements were measured using the ADHD-RS-IV rating scale. At the end of the 4-week study, children in the active group had a decrease of 27% vs 16% among children in the placebo group. Additionally, 52% of children in the treatment group showed a clinically meaningful improvement in ADHD symptoms as compared to 14% in the placebo group.

Even though the ADHD-RS scores got worse in both groups after the treatment was stopped, they remained lower in the eTNS group, suggesting that the treatment was durable. No child in either group discontinued treatment.



More information on the Monarch eTNS clinical studies is available on the company's website **www.neurosigma.com/journal-articles.html** and in the device user manual.

A low-risk treatment option

The most common side effects observed with eTNS use include drowsiness, an increase in appetite, trouble sleeping, teeth clenching, headache, and fatigue. In the clinical trial, trouble sleeping occurred about equally in the active treatment and the sham treatment group. No serious adverse events have been associated with use of the device. **For full safety information, please consult the instructions for use.**

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external Trigeminal Nerve Stimulation for
Attention Deficit Hyperactivity Disorder

Now, for children ages 7-12 years with ADHD who are not on medication

An FDA-cleared treatment device that works at night

The Monarch eTNS System is easier to get than you think

Ask your doctor for a prescription

If you are interested in participating in the Monarch Pediatric Care Program, and your physician agrees that the Monarch eTNS System is right for your child, ask your doctor to fill out the enrollment form and fax it directly to 703-832-8447. You can obtain a copy of the enrollment form by using this convenient QR code. You will be contacted by the Monarch Pediatric Care Program to discuss next steps.

SCAN TO GET YOUR ORDER FORM

The Monarch Pediatric Care Program will contact your insurance company to determine coverage and work with your healthcare provider on any prior authorizations needed. Our team of patient support advocates will work with you on navigating the complex insurance environment and assist in finding a fulfillment partner. We can also assist in determining the best purchasing options for your family's budget.

For additional assistance, you can contact the Monarch Pediatric Care Program at: 877-765-7660

Ask your doctor today about this innovative, low-risk, non-medication option for treating children with ADHD

Learn more at **www.monarch-etns.com**

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