Monarch eTNS® System
by NeuroSigma

external Trigeminal Nerve Stimulation for Attention Deficit Hyperactivity Disorder

A non-medication treatment option for children with ADHD

Available by prescription only

About the size of an Apple TV controller, 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.

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

The Monarch eTNS System is the first FDA-cleared device for ADHD with proven efficacy in alleviating ADHD symptoms. This non-medication, minimal-risk monotherapy is used by parents or caregivers for at-home treatment of children ages 7 to 12 years old who are not currently taking prescription medication for ADHD.

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.

A neuromodulation device to improve ADHD symptoms in children aged 7-12 years

Therapy backed by neuroscience

The Monarch eTNS® System targets the neurologic underpinnings that lead to ADHD, helping to regulate brain areas linked to ADHD symptoms via the trigeminal nerve. This high bandwidth pathway to the brain stem and prefrontal cortex is tied to a key brain region associated with attention, mood, anxiety, and executive control of behavior. By using mild stimulating pulses delivered to nerve branches through the skin of the forehead, the Monarch eTNS System increases neuronal activity in these brain areas and decreases excitability. Neuroimaging and EEG studies have documented these effects.

A non-medication prescription monotherapy designed for bedtime use overnight

The Monarch eTNS System:

- A cell phone-sized device that connects to a disposable adhesive patch that is placed on the child's forehead at bedtime
- The device sends low stimulating pulses to the trigeminal nervethrough the patch overnight
- The pulsing effects are mild and typically not intrusive, and childrenhave described the stimulation as a tingling sensation on the skin
- The device is intended to be used under the supervision of a caregiver during periods of sleep
- In the morning, when the child wakes up, the patch is removed

The Monarch eTNS System is convenient and easy for parents to use. Because it is a non-medication option, the device meets the needs of parents and caregivers who have fears about jumping right to psychotropic medications. Clinical trials suggest that a response to eTNS may take up to 4 weeks to become noticeable.

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.

Device performance established in 2 clinical trials [1,2]

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

64%
improved

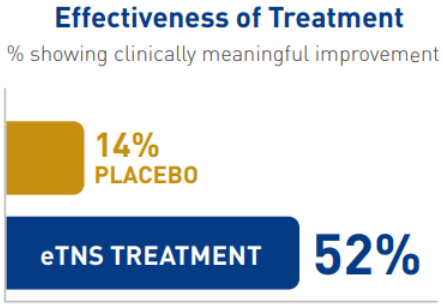
After 4 weeks of nightly use:
64% of the children were rated as "improved" or "improved very much" on a parent-completed rating scale

71%
improved

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.

References:
1. McGough JJ, Loo SK, Sturm A, et al. An eight-week, open-label pilot feasibility study of trigeminalnerve stimulation in youth with attention-deficit/hyperactivity disorder. Brain Stimulation. 2015;8:299-304.
2. McGough JJ, Sturm A, Cowen J, et al. Double-blind, sham-controlled, pilot study of trigeminal nerve stimulation for attentiondeficit/ hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2019;58(4):403-411.

The Monarch eTNS® System is available to physicians and patients through the Monarch Pediatric Care Program

If you have a patient who you think would be appropriate for the Monarch eTNS System, and are interested in participating in the Monarch Pediatric Care Program, fill out the attaced enrollment form. You will be contacted by a representative of the Monarch Pediatric Care Program to discuss next steps.

The Monarch Pediatric Care Program will contact the parent's insurance company to determinecoverage and work with you on any prior authorizations needed. The Care Program team of patient support advocates will work with parents to navigate the complex insurance environment and assist in finding a fulfillment partner. Care Program team members can also assist in determining the best purchasing options for the family's budget.

For additional assistance, contact the Monarch Pediatric Care Program at 424-248-3398

Find out today about this innovative, low-risk, non-medication option for treating children with ADHD

The Monarch eTNS System should:
- 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 used in the presence of electric monitoring equipment (e.g. cardiac monitors)
- Not be used in the bath or shower

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

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Monarch Prescription Form

The information you provide will be used by NeuroSigma, its affiliates, and service providers for your patient's enrollment in the Monarch Pediatric Care Program. You may withdraw from the program any time. For more information, please call 424-248-3398.

Please fax or email completed forms to 310-479-3114 or orders@neurosigma.com

PATIENT INFORMATION

Patient First Name _____ Patient Last Name _____

Date of Birth _____ Gender _____

Parent/Caregiver Name _____ Relationship to Patient _____

Parent/Caregiver Phone _____ Alternate Phone _____

Address _____ City _____

State _____ Zip _____ Email Address _____

PRESCRIBER INFORMATION

HCP Name _____

Clinic Name _____ Clinic Contact _____

Address _____ City _____

State _____ Zip _____ Email _____

Phone _____ Fax _____

NPI _____ State License _____ Tax ID _____

PRESCRIPTION INFORMATION

☐ Monarch eTNS Starter Kit (comes with Monarch device and 4-week supply of disposable patches)

☐ Disposable electric patches (dispensed in packages of 7 – 1 week supply) Month(s) Supply = _____

DISPENSE AS WRITTEN – THERE IS NO SUITABLE ALTERNATIVE TO THE MONARCH OR PATCHES

I certify that the above device is medically necessary, and that the information provided is accurate to the best of my knowledge. By my signature, I also acknowledge that I have obtained the patient's authorization to release the above information and such other information as may be required by the Monarch Pediatric Care Program to provide the offerings selected. I appoint the Monarch Pediatric Care Program, on my behalf, to convey this prescription to the dispensing pharmacy or durable medical equipment distributor of the patient's choice. I further certify that (a) any offering provided through this program on behalf of any patients not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use the Monarch Pediatric Care Program or any other product or service for anyone, and that (b) my decision to prescribe the products set forth on this page and request NeuroSigma Navigator Service offerings for my patient was based solely on my determination of medical necessity as set for herein, and that (c) I will not seek reimbursement for any offering provided by or through this service from any government program or third-part insurer.

Prescriber Signature_____ **Date** _____

CLINICAL INFORMATION

Diagnosis ☐ F90 ☐ F90.1 ☐ F90.2 ☐ F90.8 ☐ F90.9 ☐ Other ICD-10 Code _____

Please include copies of additional clinical documentation as necessary

AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

This Authorization allows my healthcare providers and my durable medical equipment or pharmaceutical suppliers (together, "healthcare providers") and health plans to disclose to NeuroSigma, Inc. and its third-party contractors, agents, and assignees (together, "NeuroSigma") protected health information ("PHI") about me related to my use or need for the products covered by the Monarch Pediatric Care Program. My PHI will include spoken or written facts, copies of my medical or other records from my healthcare providers, health plan or other sources outlining my medical history, treatment/management plan and other social determinants of health, as well as my insurance benefits and coverage information. The purpose of the disclosure and use set out above is to allow NeuroSigma to verify and/or obtain insurance coverage for the NeuroSigma products specified and to advise NeuroSigma with regards to the best form of communication to meet my needs. I understand that: (1) Once my PHI has been disclosed to NeuroSigma it may no longer be protected by federal privacy law and may be re-disclosed by NeuroSigma as a result. (2) I can refuse to sign this Authorization without impacting the start, continuation, or quality of my treatment, payment for treatment, clinic or insurance enrollment, or eligibility for insurance benefits or coverage because my healthcare provider and/or health plan cannot condition treatment, payment, enrollment, or eligibility for benefits on whether I sign this Authorization, but I will not be able to receive services from the Monarch Pediatric Care Program. (3) I may revoke, cancel or withdraw this Authorization at any time and for any reason by sending a signed written letter to the Monarch Pediatric Care Program at the following address: 45610 Woodland Road, Suite 320, Sterling, VA 20166. (4) If I cancel this Authorization, such cancellation will not change any actions that NeuroSigma or others took in reliance upon this Authorization before the date that I cancelled this Authorization. (5) This Authorization expires when my consideration for or participation in the Monarch Pediatric Care Program ends. (6) I have the right to receive a copy of this form from NeuroSigma. I give my permission to allow NeuroSigma to provide me with information about NeuroSigma products, disease education and awareness management programs, and promotional materials related to my condition or treatment.

Parent (or Patient's Representative) Signature _____ **Date** _____