Introducing the Monarch® eTNS® System—for treating pediatric ADHD

Treat Pediatric ADHD Without Medication
Attention deficit hyperactivity disorder (ADHD) is a neurological condition that affects millions of children, influencing behavior, mood, and focus. While medication is a common treatment, it doesn’t always work or is not preferred for many children. The Monarch eTNS System by NeuroSigma, Inc. is a new FDA-cleared treatment option for children ages 7 to 12 who are not currently taking medication for ADHD.

How can I get the Monarch eTNS System for my child?
The Monarch System is available by prescription only through NeuroSigma’s Early Access Program. If you are interested in participating, and your physician agrees that the Monarch System is right for you, ask your doctor to fill out the order form and fax it directly to NeuroSigma. You will be contacted by NeuroSigma to arrange payment and provide shipping information.

How does eTNS treat pediatric ADHD?
The name “eTNS” stands for external trigeminal nerve stimulation. The trigeminal nerve is the largest nerve in the brain (cranial nerve). It begins deep inside the brain and has branches that end close to the skin’s surface just above the eyebrows where it can receive electrical pulses through the skin. The Monarch eTNS System stimulates the trigeminal nerve, which activates parts of the brain thought to be involved in ADHD. Neuroimaging studies have shown that eTNS increases activity in brain regions that are known to be important in regulating attention, emotion, and behavior.

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Treatment with the Monarch eTNS System is easy and convenient.

The Monarch System includes a small device, which is about the size of a cell phone, that sends mild electrical signals through a wire to a disposable patch that sticks to the patient’s forehead just above the eyebrows. The Monarch eTNS device is designed for use in the home at bedtime each night under the supervision of a caregiver. Patients describe the stimulation as a tingling sensation on the skin.

How long do Monarch eTNS treatments take to work?

Clinical trials suggest that a response to eTNS may take up to 4 weeks to become noticeable. The performance of the device was assessed compared to a sham (placebo) device based on improvement in ADHD-RS (an assessment for ADHD symptoms) after 4 weeks. The results of the main clinical study for the device showed that patients who were treated with the Monarch eTNS improved significantly more than patients who were treated with a sham (placebo) device. Consult with your child’s doctor after 4 weeks of use to assess treatment effects.

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.

Are there side effects?

The most common side effects observed with eTNS use include drowsiness, an increase in appetite, trouble sleeping, teeth clenching, headache and fatigue. No serious adverse events have been associated with use of the device. For full safety information, please consult the instructions for use.

How much does the Monarch eTNS System cost?

The price for the Monarch eTNS System starter kit is $980. The starter kit includes everything needed to begin therapy including the controller unit and a 4-week supply of electric patches. Refill electric patches are sold in packages of 7, which cost $70.

Will my medical insurance reimburse me for the Monarch eTNS System?

Typically, new products approved for the treatment of ADHD are not immediately reimbursed by patients’ insurance. Reimbursement tends to become available over time. NeuroSigma will work diligently with our customers and insurance companies to try and obtain coverage for the Monarch eTNS System by as many insurance plans as possible. Patients who currently have a Health Savings Account (HSA) or Flexible Spending Account (FSA) may be able to use those funds to cover the cost of the device.

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, 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. 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). The Monarch eTNS® System, the Monarch NS-2 Electric Patch, and related brand marks are trademarks of NeuroSigma, Inc. No use of any NeuroSigma trademark, trade name, or trade dress in this site may be made without the prior written authorization of NeuroSigma, except to identify the product or services of the company. The product images are for illustrative purposes only.