About gammaCore[™] (non-invasive vagus nerve stimulator)^{1,2}

gammaCore is a proprietary, non-invasive neuromodulation therapy delivered by a hand-held unit that stimulates the vagus nerve through the skin. gammaCore is FDA cleared to acutely treat pain associated with migraine and episodic cluster headache, by activating the vagus nerve with a gentle, electrical stimulation.

gammaCore was created by electroCore, Inc., a U.S.-based commercial-stage bioelectronic medicine company. gammaCore provides patients with an effective option to treat as needed, without the potential side effects associated with commonly prescribed medicines.



How to Use gammaCore 1,2,3

Designed as a portable, easy-to-use treatment that can be self-administered by patients (as needed)



Patients apply a conductive gel to the stimulation surfaces before placing on neck



Two-minute stimulations (characterized as a mild electrical pulse) activate the vagus nerve, which plays an important role in regulating pain



The stimulation of vagus nerve fibers may lead to a reduction of pain, without many of the side effects associated with drugs and invasive surgical procedures

About Cluster Headache⁴



Rare primary headache disorder characterized by recurring unilateral attacks



Extreme headache pain high enough in severity to garner the nickname "suicide headaches"



Bouts occur rapidly and with variable frequency, but often at the same time each year or day



Attacks are more frequent at night

About Migraine⁵



Migraine is a class of recurrent, pulsing headaches that are typically unilateral (on one side of the head) but may occur bilaterally (on both sides of the head)



Migraine can be accompanied by one or more disabling symptoms such as: visual disturbances, nausea, vomiting, dizziness, extreme sensitivity to sound, light, touch and smell, and tingling or numbness in the extremities or face



Migraine affects more than 36 million people in the U.S.







Important Safety Information

gammaCore (non-invasive vagus nerve stimulator) is indicated for the acute treatment of pain associated with episodic cluster headache and migraine in adult patients.

- The safety and effectiveness of the gammaCore (nVNS) has not been established in the acute treatment of chronic cluster headache.
- gammaCore has not been shown to be effective for the prophylactic treatment of migraine headache, chronic cluster headache, or episodic cluster headache.
- The long-term effects of the chronic use of gammaCore have not been evaluated.
- Safety and efficacy of gammaCore has not been evaluated in the following patients, and therefore is NOT indicated for:
 - Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
 - Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
 - Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
 - Pediatric patients
 - Pregnant women
 - Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia
- Patients should not use gammaCore if they:
 - Have a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
 - Are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

Note: This list is not all inclusive. Please refer to the gammaCore <u>Instructions for Use</u> for all of the important warnings and precautions before using or prescribing this product.

gammaCore is available by prescription only. U.S. Federal Law restricts this device to sale by or on the order of a licensed healthcare provider.

1. gammaCore Instructions for Use. Basking Ridge, NJ: electroCore, Inc.; 2018.

- 2. gammaCore Important Safety Information. Basking Ridge, NJ: electroCore, Inc.; 2018.
- 3. Yuan H, Silberstein SD. Vagus nerve and vagus nerve stimulation, a comprehensive review: part I. Headache. 2016;56(1):71-78.
- 4. "Cluster Headache." The Migraine Trust. The Migraine Trust, n.d. Web. 30 Nov. 2016. https://www.migrainetrust.org/about-migraine/types-of-migraine/other-headache-disorders/cluster-headache/.
- 5. Migraine facts. Migraine Research Foundation. http://migraineresearchfoundation.org/about-migraine/migraine-facts/. Accessed February 2018.



