

Warnings and Precautions - Important Safety Information gammaCore™ (non-invasive vagus nerve stimulator)



Warnings indicate instructions, which, if not followed, may result in serious injury or death to the device user or to the patient.



Precautions indicate instructions, which, if not followed, may result in damage to the equipment or degradation in the quality of treatment.

Indications

gammaCore Sapphire™ non-invasive vagus nerve stimulator (nVNS) is indicated for:

- The preventive treatment of migraine headache in adolescent (age 12 and older) and adult patients
- The acute treatment of pain associated with migraine headache in adolescent (age 12 and older) and adult patients
- Adjunctive use for the preventive treatment of cluster headache in adult patients
- The acute treatment of pain associated with episodic cluster headache in adult patients
- Treatments of hemicrania continua and paroxysmal hemicrania in adults



Warnings

- The safety and effectiveness of gammaCore (nVNS) have not been established in the acute treatment of chronic 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 and therefore is NOT indicated for:
 - Adolescent patients with congenital cardiac issues
- Safety and efficacy of gammaCore have not been evaluated in the following patients:
 - Patients with uncontrolled hypertension, hypotension, bradycardia, or tachycardia
 - Patients with a history of baseline cardiac disease or atherosclerotic cardiovascular disease, including congestive heart failure, known severe coronary artery disease, or recent myocardial infarction (within 5 years)
 - Patients with metallic device such as a stent, bone plate or bone screw implanted at or near their neck
 - Patients with a history of abnormal baseline ECG, prolonged QT interval or arrhythmia
 - Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
 - Pediatric patients (less than 12 years of age)
 - Pregnant women
 - Patients with active cancer or cancer in remission
 - Patients with an abnormal cervical anatomy
 - Patients with a history of brain tumor, aneurysm, bleed or head trauma
 - Patients with a history of syncope or seizures
- Contact your HealthCare Provider (HCP) if your symptoms continue or worsen.
- Treatment is intended to be given (administered) as directed by an HCP. Your HCP or an electroCore Customer Service Representative must train you in the proper use of gammaCore.



Precautions

- The long-term safety and effectiveness of gammaCore have not been demonstrated in adolescents 12-17 years of age. Due to hormonal and cognitive development changes in adolescents, this population should be closely monitored while using the device. The use of the device in this population is based on extrapolated data from a clinical study in adults.

Before Use:

- You must carefully read the gammaCore Instructions for Use.
- Only use gammaCore as described in the Instructions for Use, or as otherwise directed by the HCP.
- The use of more than 24 stimulations per day has not been evaluated in controlled clinical trials. Do not use more than 24 stimulations in a 24-hour period.
- Only use an electroCore-approved gel with gammaCore. Please contact Customer Service for an electroCore-approved gel that works with the device.
- Do not share gammaCore with another person.
- gammaCore should not be applied across or through the head, directly on the eyes, covering the mouth, on the chest or the upper back, or over the heart.
- Remove jewelry that may touch the treatment location (necklaces, earrings, etc.).
- Carefully examine the device for any signs of damage or defects.

Do not use gammaCore if:

- The stimulation surfaces are broken or cracked.
- The casing is cracked, dented, or appears to be damaged.
- An "E" with a numeric code is displayed on the screen when the device is turned on. This means that there is an error.
- It has passed its expiration date. The expiration date is indicated on the device packaging.

During Treatment:**Discontinue treatment if you experience:**

- Light-headedness, dizziness, or chest pain
- Excessive skin irritation

If the device seems to malfunction, discontinue use immediately, continue taking usual medications and seek medical care as needed. When possible, contact Customer Service for assistance with your device; Customer Service cannot provide medical assistance.

Caring for Your Device:

- Keep gammaCore away from water or other liquids, including cleaning liquids.
- Moisture may damage the device. Keep gammaCore away from items such as nebulizers and steam kettles.
- Store gammaCore in a safe location out of reach of children.
- Avoid exposure to extreme hot or cold temperatures outside the range of 32°F to 100°F (0°C to 38°C). Exposure to such conditions may cause the device to malfunction.
- Do not attempt to replace the device battery. If the device is not working, contact Customer Service.
- Do not open or take apart the case or attempt to repair or modify the device. There are no user-serviceable parts. If the device is not working, contact Customer Service.
- As the device contains a lithium-ion battery, do not intentionally damage, burn, or puncture the device.
- Wireless communications equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies, can affect this equipment. Keep gammaCore at least 3.3 m (10.8 ft) away from these items while in use.

Contraindications

Contraindications include but are not limited to:

- Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
- Patients who are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

Patients should not use gammaCore:

- While driving, operating machinery, or during any activity that may put patient at risk of injury
- Near microwave machines, magnetic resonance imaging, radio frequency surgical, or computer-aided tomography machines
- In an explosive atmosphere or in the presence of flammable gas mixtures
- If patient has an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on the neck at the treatment location
- If patient has wet skin, is in the water, or just stepped out of the water (e.g., shower, bath, pool)

Safety and Performance

Please visit www.gammacore.com/prescribing-gammacore/clinical-efficacy for additional Performance and Safety information.

Caution: For Prescription Use Only. US Federal Law restricts this device to sale by or on the order of a licensed healthcare provider.