

# INFORMATION FOR PATIENTS

## gammaCore™ non-invasive Vagus Nerve Stimulation



### gammaCore Sapphire™ (non-invasive vagus nerve stimulator) provides non-invasive vagus nerve stimulation (nVNS) on the side of the neck.

In Australia, gammaCore is indicated for the treatment and/or prevention of primary headache (migraine, cluster headache, and hemicrania continua) and medication overuse headache in adults.

gammaCore is available in Australia on authorisation by a registered healthcare professional. It is important to discuss your suitability for gammaCore nVNS therapy, with your healthcare professional.



gammaCore provides a mild electrical stimulation to the vagus nerve, which runs through the neck and carries information to the central nervous system.

Each stimulation with gammaCore lasts 2 minutes. After 2 minutes, the device automatically stops delivering the stimulation and turns itself off. The patient controls the intensity level.

gammaCore stimulation feels like a tingling sensation on the side of the neck where the device is held. A downward pulling on the lip is commonly experienced and is a good indicator of the correct treatment position.

In each 24 hour period, you will have access to 30 gammaCore stimulations, starting when the device is turned on and the intensity level is increased above 3. Once the maximum daily number of stimulations has been reached, the device will not deliver any more stimulations until the start of the next 24- hour period. The number of remaining stimulations available in a 24-hour period is indicated on the display.

gammaCore is rechargeable and includes a charging case to charge the device. A gammaCore refill card is used to load the device with days of therapy based on a healthcare professional authorisation.

Once activated with a refill card, the course of therapy will decrease by one day as every 24- hour period passes. This daily countdown will occur regardless of use, so only activate a refill card when you intend to use the full course of therapy.

gammaCore is supplied non-sterile and is a single patient use device.

# gammaCore is used as both a preventive and acute therapy.

## PREVENTIVE TREATMENT

**Each day, deliver two preventive stimulations, morning and night.**

Complete 2, two-minute stimulations on the same side of the neck at morning and night.

Additional treatments may be recommended by your Healthcare Professional.



## ACUTE TREATMENT

**At the earliest sign of pain:**

Complete 2, two-minute stimulations on the same side of the neck as needed; repeat treatment if pain persists.



### 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

### Do 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 mixture
- If there is an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on the neck at the treatment location
- On wet skin, in the water, or having just stepped out of the water (eg, shower, bath, pool)

### The most common side effects (occurring in less than 2% of patients) include the following:

- Application site discomfort
- Application site irritation/redness
- Local pain, face/head/neck area (including toothache)
- Muscle twitching and/or contractions, face/head/neck area (including facial droop and/or lip pull)
- Headache/migraine
- Dizziness
- Tingling, pricking, or a feeling of “pins and needles” on the skin where the device is applied (paraesthesia/dysesthesia)

These side effects typically resolve immediately after the stimulation is complete.

For Full Safety Information – please see the gammaCore Instructions for Use.

Always follow the gammaCore Instructions for Use.

### Using gammaCore with other medications and other treatments

Your healthcare professional will provide advice regarding your ongoing treatment routine, including the use of any additional therapies and/or medications. It is important to always follow their recommendations about your medications. gammaCore can be used with existing medications as there have been no reported device-drug interactions.

### Starting gammaCore therapy

Your Healthcare Professional will complete the Medistar gammaCore Authorisation and Consent Form, if you are suitable for gammaCore therapy. They will discuss the safety information with you and discuss how to use the gammaCore device. They will provide you with the initial and ongoing costs and the Starter Kit options.

You will complete the Consent section on the bottom of the form.

Once we receive the form at Medistar, you will be contacted by one of the Customer Service team regarding your payment and shipment of your gammaCore Starter Kit. You will then be provided with links to educational videos and details on how to access additional product support if required.

### For more Information:

If you or your Healthcare Professional require any additional information about gammaCore non-invasive vagus nerve stimulation therapy, please contact us at:

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