

# CEFALY Medical FAQs

## PRE-EXISTING CONDITIONS

### **Is CEFALY safe to use with a spinal cord stimulator?**

CEFALY is not contraindicated in the presence of a spinal cord stimulator. For safety reasons, we recommend the following conditions are met prior to use with CEFALY (1) ensure all metallic or device portions of the spinal cord stimulator are below the level of the 2nd cervical vertebrae or C2 level and (2) if possible, turn off the spinal cord stimulator when the CEFALY device is in use.

### **Is CEFALY safe to use with brain lesions?**

CEFALY was not studied in patients with known brain lesions. The effectiveness and safety of CEFALY for patients with certain brain lesions (stroke, hemorrhage, tumors, etc.) is not known. Brain lesions are a very non-specific term and can vary widely in their cause, pathology, and prognosis. We recommend that you discuss the risks and benefits of starting CEFALY with a neurologist in the setting of known brain lesions.

### **I have a brain aneurysm, tumor, epilepsy, or stroke, is the CEFALY a contraindication?**

If you have a history of any of these conditions, it is best to discuss them with your healthcare provider prior to starting CEFALY treatments.

### **Will CEFALY work for Trigeminal Neuralgia?**

The effectiveness and safety of CEFALY for Trigeminal Neuralgia is unknown. CEFALY has shown effectiveness and safety for:

- The rescue (acute) treatment of migraine attacks with or without aura in patients 18 years of age or older.
- The prevention of recurring (episodic) migraine in patients 18 years of age or older.

### **I have allodynia. Can I use CEFALY treatments?**

Allodynia is a symptom consisting of increased sensitivity to touch. People with allodynia may perceive painful sensations from objects or items that do not typically cause pain. Allodynia can affect your tolerance to nerve stimulation treatments.

If you experience allodynia, you should discuss these symptoms with your healthcare provider before starting CEFALY treatments. We recommend people with allodynia become familiar with the intensity stabilization function before using the CEFALY device.

### **Will CEFALY work for Vestibular Migraines?**

The effectiveness and safety of CEFALY for vestibular migraine is unknown. CEFALY has shown effectiveness and safety for:

- The rescue (acute) treatment of migraine attacks with or without aura in patients 18 years of age or older.
- The preventative treatment of recurring (episodic) migraine in patients 18 years of age or older.

### **Will CEFALY work for chronic migraine?**

CEFALY is FDA-approved for the preventative and acute treatment of episodic migraines. If you have chronic migraine, it is best to discuss with your healthcare provider prior to starting CEFALY treatments.

### **Will CEFALY work for Intractable Migraine?**

CEFALY has not been systematically studied in the treatment of intractable migraines. If you suffer from intractable migraine, it is best to discuss with your healthcare provider prior to starting CEFALY treatments.

### **Will CEFALY work for my migraines that usually start from and affect the back of my head (occipital area)?**

Migraines may involve a variety of headache locations and patterns. The majority of migraine headaches start or affect one side of the head. If you experience headaches that start in the back of your head, or if your headaches have an unusual location or pattern, it is best to check with your healthcare professional to exclude other causes of your headaches prior to starting CEFALY treatments.

### **Will CEFALY work for TBI (Traumatic Brain Injury) patients?**

The effectiveness and safety of CEFALY treatments for headaches in patients with Traumatic Brain Injury are unknown. If you have headaches associated with a history of Traumatic Brain Injury, it is best to discuss with your healthcare provider prior to starting CEFALY treatments.

### **Are CEFALY treatments for migraine safe to use with Epilepsy / history of seizures?**

Epilepsy or recurrent seizures is not a contraindication for CEFALY treatments, however, CEFALY treatments were not specifically studied in patients with epilepsy or a history of seizures. Additionally, CEFALY treatments are contraindicated in patients with metal components or devices inside or surrounding the skull. If you have a history of epilepsy surgery, including placement of a vagal nerve stimulator (VNS), you should discuss it with your epileptologist or neurosurgeon prior to starting CEFALY treatments.

### **Can CEFALY be used if I have an intracranial tumor or cancer?**

The effectiveness and safety of CEFALY in patients with an intracranial tumor or cancer is unknown. If you have a history of these conditions, it is best to discuss with your healthcare provider prior to starting CEFALY treatments.

### **Is CEFALY safe to use during pregnancy?**

CEFALY is NOT contraindicated in pregnancy. However, the safety of CEFALY treatments in pregnancy has not been established in clinical studies. You should consult your healthcare provider prior to CEFALY treatments if you are planning to become pregnant or are pregnant.

### **My child is less than 18 years old, but CEFALY is indicated for ages 18 and over. Can my child use CEFALY?**

The effectiveness and safety of CEFALY treatments in patients younger than 18 years of age is unknown. If your child experiences migraines, we recommend that you discuss with your child's healthcare provider for any further questions regarding use in persons under the age of 18.

### **Can I use CEFALY with other migraine medications?**

There are no contraindications of CEFALY treatments with other medications. Some CEFALY users may experience sleepiness with treatments. Therefore, caution is advised for patients starting CEFALY who are also taking sedative medications.

### **Can I use CEFALY if I have fibromyalgia?**

There are no contraindications of using CEFALY for migraine treatment in patients with fibromyalgia. If you have a history of fibromyalgia, please discuss with your healthcare provider prior to starting CEFALY treatments.

### **My migraines started after age 50. Can I use CEFALY?**

Most migraine headaches start before 50 years of age. New-onset headaches after age 50 raise the possibility of non-migraine-related causes. If you started experiencing migraines after age 50, we recommend an evaluation by a healthcare provider prior to starting CEFALY.

**Will CEFALY help with my migraine auras?**

The effect of CEFALY treatments on migraine auras is unknown at this time.

## USAGE

**How many times can / should I use the CEFALY ACUTE treatments per day?**

Each CEFALY ACUTE treatment lasts for 60-minutes. CEFALY ACUTE treatments are best utilized early in the migraine attack or during migraine aura(s). The CEFALY ACUTE treatment can be used consecutively for up to two (2) sessions (i.e., 2 hours). The effectiveness and safety of CEFALY ACUTE treatments, greater than 2 hours per day, has not been established in clinical studies.

Daily CEFALY PREVENT treatments (20-minute duration) can be used the same day as CEFALY ACUTE treatments.

**Do I have to use the CEFALY PREVENT at nighttime as recommended?**

CEFALY PREVENT 20-minute daily treatments can be used anytime during the day or evening. A common side effect of CEFALY treatments includes sleepiness after use. Many migraine sufferers may experience difficulty falling asleep and therefore prefer CEFALY PREVENT treatments prior to bedtime in order to transition to sleep. Though we encourage you to rest during therapy, CEFALY treatments should be avoided while sleeping.

## **How long does it take before I start seeing results?**

Though clinical studies have demonstrated efficacy / results with CEFALY using the maximum stimulation intensity, you may experience migraine relief using CEFALY at lower stimulation intensities. When starting CEFALY treatments, the target intensity will vary from person to person. In general, the stimulation should be comfortable / tolerable without adverse effects for the entire duration of the treatment. The big-picture is to reach long and short-term migraine relief with a tolerable level of stimulation. Over time, your nerves may become accustomed to the stimulation intensity, and you may consider gradually allowing higher treatment intensities. It is common for headaches to become slightly worse during the initial minutes of CEFALY treatment; however, the treatments should not be painful before stabilization. Please refer to our instructional video “Controlling the Intensity.”

In clinical studies, once the full simulation is tolerated, relief from migraine attacks using the CEFALY ACUTE treatments are generally expected within the first five treatment sessions. CEFALY ACUTE often provides migraine relief as soon as the first treatment session. In a clinical trial, 29% of migraine sufferers reported complete migraine relief after 1-hour initial use of CEFALY ACUTE treatment. In the same study, 63% of migraine sufferers experienced a 50% or more reduction in their migraine severity pain at 1 hour after initial use of CEFALY ACUTE treatment. In addition, the effect of reduced average migraine severity was sustained over a 24-hour period.

For CEFALY PREVENT treatments, some users begin to see benefits within 6-8 weeks; however, most users see results by three months.

## **After using CEFALY for a few weeks to months, the stimulation does not seem to be as strong. Is the device still working?**

If you use Cefaly regularly, you may eventually perceive the stimulation from the device to be less intense over time. This is normal and your device is not defective or malfunctioning. For experienced CEFALY users who are accustomed to the lower stimulation intensities, the intensity can be rapidly increased by pressing and holding the device button after the first 10 seconds of starting a treatment. Please refer to the user manual section titled “Manually Increasing the Intensity During First 14 Minutes.”

### **Why can I only feel CEFALY stimulation on one side of my head?**

It is always good practice to ensure proper application of the adhesive pads and CEFALY device. Please refer to the video “How to Use the CEFALY migraine treatment device”.

For people with migraines, it is common to have increased sensitivity on one side of the head. If the device is properly applied, the device is still working even though you may not feel the treatment equally on both sides.

### **What are the long-term side effects to using CEFALY treatments? Is CEFALY safe to use long term?**

In all clinical trials, there were no serious adverse side effects, and all side effects of CEFALY ACUTE and PREVENT treatments were temporary and completely reversible. The long-term effects (greater than 90 days) of regular CEFALY use are unknown.

The longest clinical trial of CEFALY PREVENT treatments evaluated safety over 90 days or 3 months. There were no adverse events or side effects reported during this study. In a survey of 2,313 CEFALY users across three countries, side effects were reported in 4.3% of users during a 40-day at-home trial period. All reported side effects were minor and fully reversible.

### **What should I do if I experience skin dryness on my forehead after CEFALY sessions?**

If the electrodes are stored, applied, and changed according to the recommended usage, skin dryness at the electrode site may be related to frequent electrical stimulation.

If you experience local skin dryness with repeated stimulations, refrain from additional CEFALY treatments until the rash or dryness completely resolves. Skin moisturizers may help facilitate skin recovery and should be continued once CEFALY treatments are resumed. If you experience repeated skin dryness, hypoallergenic electrode pads are available via special order or through your CEFALY representative. Allergic skin reactions to the electrode pad are rare and may also improve with hypoallergenic electrode pads. You can contact a CEFALY representative via [info@cefaly.com](mailto:info@cefaly.com).

**When using CEFALY, I experience the “pins and needles” sensation which is often uncomfortable. Is this normal?**

Paresthesias (pins-and-needles sensation) of the head and stimulation area is the most common symptom encountered when starting CEFALY treatments. This is most commonly encountered when first starting CEFALY treatments.

If you are first starting CEFALY, it is important that you understand the stabilization feature of the CEFALY device prior to use. Please refer to our instructional video “Understanding the intensity”. Early stabilization is your primary tool to minimize uncomfortable paresthesia sensations when starting CEFALY treatments. Over time, the tolerance to stimulation may improve allowing for higher intensities without uncomfortable paresthesia sensations.

If you experience paresthesias during CEFALY use, the sensations should subside within a few hours after CEFALY use. If symptoms of paresthesias persist for greater than 24 hours, stop CEFALY treatments and contact us at [info@cefaly.us](mailto:info@cefaly.us).

## METAL

**Can I use CEFALY with a ventriculoperitoneal (VP) shunt?**

In general, there are two types of ventriculoperitoneal (VP) shunts; programmable and non-programmable. Programmable VP shunts contain metallic or electrical components. The use of CEFALY is contraindicated with programmable VP shunts. Non-programmable VP shunts are commonly made from silicone and are safe with the use of CEFALY. It is always a good practice to check with your healthcare provider prior to using CEFALY to ensure your VP shunt does not contain any medical or electrical components.

**I have a metal plate / screw / any metal object - in either my forehead or head, is that a contraindication?**

Yes. The presence of a metal plate, screw, or implant of the head is an FDA contraindication to CEFALY use.

**Can I use CEFALY with metal piercings?**

It is recommended for patients to remove any metallic jewelry around their head or neck region whenever using the CEFALY device. This includes tongue piercings, eyebrow piercings, and nose rings.

## DIFFERENT TYPES OF HEADACHE

### **Will CEFALY work for Cluster Headaches?**

The effectiveness and safety of CEFALY for cluster headaches is unknown. CEFALY has shown effectiveness and safety for:

- The rescue (acute) treatment of migraine attacks with or without aura in patients 18 years of age or older.
- The prevention treatment of recurring (episodic) migraine in patients 18 years of age or older.

### **I have tension headaches. Is CEFALY indicated for that?**

CEFALY has a primary indication for migraine treatment however CEFALY may also have effectiveness in treating tension-type headaches.

### **Will CEFALY work for Daily Persistent Headache?**

The effectiveness and safety of CEFALY for daily persistent headache has not been established in clinical studies. If you experience daily persistent headache, please discuss with your primary care provider prior to starting CEFALY treatments.

## HEART

### **Is CEFALY contraindicated in patients with implanted cardiac devices (i.e., pacemaker, loop monitor, defibrillator)?**

Yes. Implanted cardiac devices (i.e., pacemakers, loop monitors, defibrillators) are listed as contraindications to CEFALY use according to the US Food and Drug Administration.

CEFALY has not been studied in patients with implantable cardiac devices, therefore the contraindication is precautionary. The risk of inference of the CEFALY device with implanted cardiac devices is unknown. Though the risk is unknown, the potential for serious consequences of electrical dysfunction of an implantable cardiac device is a primary factor leading to the contraindication labeling.

If there are specific concerns regarding this contraindication, we recommend you discuss with your cardiologist and / or neurologist to determine the most appropriate and individualized treatment option and alternatives.

## EARS

### **I have ringing in my ears (tinnitus) after using CEFALY, is this normal?**

Tinnitus (ringing in the ears) is a potential side effect with CEFALY use occurring in approximately 1% of patients in clinical studies. Use of the stabilization feature may help to mitigate this symptom if encountered during treatment. Please refer to our instructional video “Understanding the intensity”.

Symptoms of tinnitus after CEFALY treatment should subside or improve within 24 hours. If symptoms of tinnitus persist or do not improve after 24 hours, please refrain from CEFALY treatments until symptoms completely resolve.

### **Can I use CEFALY with a Cochlear Implant?**

If you have a cochlear implant, we recommend discussing it with your ENT provider prior to starting CEFALY treatments. Implanted metallic or electronic components of the head are a contraindication for CEFALY use.

## OTHER TREATMENTS

### **Can I use it with / after / before having botulinum toxin injections (Botox) for chronic migraines?**

There is no contraindication for using CEFALY with Botox injections. If you are interested in CEFALY treatments and Botox injections, we recommend that you discuss both therapies with your healthcare provider.

If you already receive Botox injections for chronic migraine, we recommend waiting 48-72 hours after an injection before placing a CEFALY electrode and starting CEFALY treatments.

If you are new to both CEFALY and Botox treatments, we recommend starting one therapy at a time and waiting at least three months before beginning the other treatment.

### **How does CEFALY compare to Gammacore, eNeura, Nerivio (Theranic)?**

At this time, there are no clinical trials (medical studies) directly comparing the effectiveness and safety of CEFALY treatments to other acute or preventative migraine treatments. There are no contraindications of using CEFALY with other neuromodulation devices. Please discuss with your healthcare provider before using multiple headache treatment devices.

### **Can I use CEFALY with alpha-Stimulation (CES Cranial Electro Stimulation)?**

Yes. There is no contraindication of using CEFALY and CES on the same day. If you are using both therapies, please consider the following:

1. Avoid using both CEFALY and CES at the same time.
2. Both CEFALY and CES may contribute to drowsiness or sleepiness. Starting one therapy at a time may be best to determine how you respond to each treatment.

### **Can I use CEFALY and Transcranial Magnetic Stimulation (TMS)?**

CEFALY use with transcranial magnetic stimulation (TMS) has not been studied in clinical trials. If you anticipate a finite number of TMS sessions, it is recommended to complete TMS therapy prior to starting CEFALY therapy.

If you have prior exposure to TMS and have no side effects related to the treatments, then starting CEFALY may certainly be considered. If you anticipate ongoing TMS therapy, we recommend discussing it with your prescribing healthcare provider prior to starting CEFALY treatments with TMS.

## DENTAL

### **Is CEFALY safe to use with dental implants?**

Dental Implants can vary in their composition and placement. Cefaly is not recommended if you have implanted metallic components in the head. For more specific information regarding the presence of metal with dental implants, please contact or discuss with your dentist.

### **Is CEFALY safe to use with dental fillings made of metal?**

The presence of metal dental fillings, or dental amalgam, should not interfere with CEFALY treatments for migraines. If you experience dental pain with CEFALY treatments, we recommend stopping CEFALY sessions and consulting with a dentist or neurologist for further evaluation.

## EYES

### **I am experiencing blurry vision when I use CEFALY treatments, what should I do?**

If you experience blurry vision in one or both eyes during CEFALY treatments, stop the treatment session and contact your healthcare provider. Blurry vision is rarely reported with CEFALY use; however, should you experience these symptoms, do not continue to use the treatment until you contact a medical provider regarding your symptoms. All users experiencing blurry vision are also encouraged to contact our medical department for additional information and guidance.

### **My eyes are closing / hard to keep open / difficulty opening / eye heaviness / discomfort when using my CEFALY.**

Eyelid heaviness, eye twitching and eyelid paresthesias (pins and needles sensation) are common during CEFALY treatments. During initial treatments, you may notice difficulty keeping eyelids open. Please refrain from attempting to overcome or force your eyes open during initial treatments. We recommend seeking a quiet and relaxing location when first starting CEFALY treatments.

Please keep in mind that the stimulation intensity SHOULD NOT be painful. Prior to starting CEFALY treatments, it is critical to understand the stabilization feature to limit the intensity of stimulation. Please refer to our instructional video “Controlling the intensity”. Early stabilization may assist in facilitating tolerability of the stimulation intensities especially when first starting CEFALY treatments

## VOCABULARY REFERENCE

1. Allergic dermatitis is an allergic reaction of the skin, resulting in swelling, bumps, burning, itching, and vesicular formations due to a substance the skin is reacting to.
2. Chronic migraines are recurring migraines where the frequency of migraine headaches occurs 15 or more days per month.
3. Episodic migraines are recurring migraines where the frequency of migraine headaches occurs less than 15 days per month.
4. Migraine Aura is a series of sensory disturbances that happen shortly before a migraine attack. These disturbances range from seeing sparks, bright dots, and zig zags to tingling on one side of the body or an inability to speak clearly, and usually last 20-60 minutes. (American Migraine Association)
5. Preventative migraine treatments are migraine therapies used on a scheduled basis to suppress or decrease the number and / or severity of migraine attacks.
6. Rescue (acute) migraine treatments are migraine therapies used after a migraine attack or aura has started.

## REFERENCES

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Magis D, Sava S, d'Elia TS, Baschi R, Schoenen J. Safety and patients' satisfaction of transcutaneous supraorbital neurostimulation (tSNS) with the Cefaly<sup>®</sup> device in headache treatment: a survey of 2,313 headache sufferers in the general population. *J Headache Pain*. 2013 Dec 1;14(1):95.