

Is Lenire suitable for you?

Lenire is for adults over the age of 18 with subjective tinnitus. Lenire must be recommended by a trained professional.

Contraindications

Lenire is not suitable if:

- You have a pacemaker, defibrillator or any other active implantable device.*
- You are pregnant.*
- You have epilepsy or any other condition that may result in loss of consciousness.*
- You have any condition that causes impaired sensitivity of the tongue.**
- You have oral cavity inflammation, sores or lesions that may contact the Tonguetip.**
- You have any intermittent or chronic neuralgia in the head and neck area.*
- If you have Meniere's disease.* Lenire use has not been evaluated for Meniere's disease.
- If you have objective source tinnitus.
- In the presence of oral piercings.

*Unless directed by a physician.

**Unless directed by a physician or dentist.

Frequently Asked Questions



Can I purchase Lenire over the counter?

No. Lenire is customized and can only be administered by a qualified healthcare professional after a consultation.



How Long is Lenire treatment?

Lenire should be used for two 30-minute sessions daily for a treatment timeframe recommended by your tinnitus care professional.



Was Lenire's trial controlled?

Yes. Lenire designed TENT-A3 with the FDA's guidance and found bimodal neuromodulation to be a safe and effective treatment.



About Neuromod Devices

Neuromod U.S.A. Inc. is a wholly owned subsidiary of Neuromod Devices Ltd. headquartered in Illinois.

Neuromod specializes in the design and development of neuromodulation technologies to address the clinical needs of underserved patient populations who live with chronic and debilitating conditions.

Neuromod's tinnitus treatment device, Lenire, is the first non-invasive bimodal neuromodulation device shown to soothe and relieve tinnitus in a controlled large-scale clinical trial. As a result, Lenire is the first treatment device of its kind to be granted De Novo FDA approval.



Neuromod USA inc. 1011 Warrenville Road,
Suite 150 Lisle, IL 60532, USA

Website: www.lenire.com

LENIRE®
soothe tinnitus

Safe and Effective At-Home Tinnitus Treatment Technology

Lenire® is scientifically proven in a ground-breaking controlled trial to significantly reduce tinnitus severity leading to an overall improved quality of life.



A New Approach to Treating Tinnitus

Tinnitus is a complex condition that affects 10 – 15% of the population. Tinnitus involves hearing, attention and emotion centers in the brain. Lenire uses bimodal neuromodulation to treat tinnitus, a combination of tongue and hearing stimulation. This paired stimulation retrains the brain to reduce the severity of tinnitus

What is the Lenire Device?

Lenire comes with three pieces of equipment:



Controller

A lightweight handheld device that controls the time and intensity of the treatment.



Headphones

Audio customized to your hearing and tinnitus plays through Bluetooth Headphones to activate the brain's auditory nerve.



Tonguetip®

A proprietary intraoral device that sits comfortably on the tongue that delivers mild and safe pulses to stimulate the tongue.

Real World Patient Stories



"Lenire is a powerhouse of a treatment device for me."

Elliot, Engineering Executive



"I think devices like Lenire show that there is hope out there."

Vicki, Retired I.T. Manager



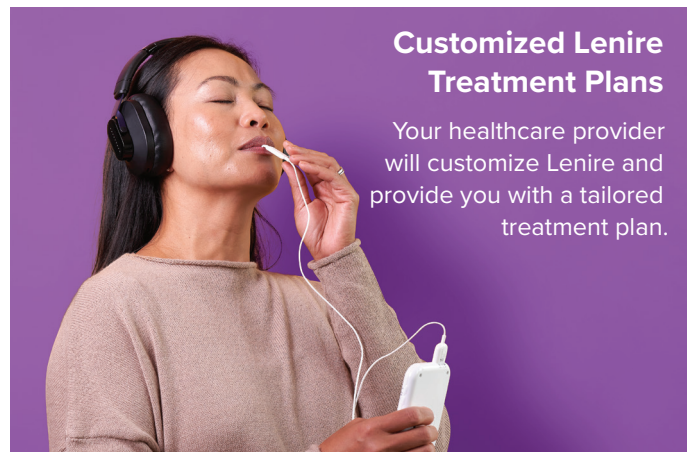
"Lenire is a game-changer. It is what I had been waiting for."

Bert, Volunteer Pilot

Watch patient stories: www.lenire.com/patient-stories

Customized Lenire Treatment Plans

Your healthcare provider will customize Lenire and provide you with a tailored treatment plan.



Typical Treatment Plan



HEARING AND TINNITUS ASSESSMENT

Visit a Lenire-qualified healthcare provider and learn if Lenire is the right treatment for you.



LENIRE DEVICE FITTING

The Lenire device is customized to your tinnitus and hearing profile.



HOME USE

Use Lenire daily as advised by your healthcare provider.



FOLLOW UP 1

Visit your provider to review progress.



HOME USE

Continue to use Lenire daily as advised by your healthcare provider.



FOLLOW UP 2

Visit your provider to review progress and discuss continued use of Lenire.

Groundbreaking Tinnitus Treatment Clinically Proven in Controlled Trial

In Lenire's most recent clinical trial, TENT-A3, Lenire was proven to be safe, effective and recommended highly by patients who used Lenire as instructed.



Clinical Trial Takeaways & US Patient Results

91.5% of 220 real world Lenire patients had a clinically significant improvement in tinnitus.⁵

71% of those with moderate or worse tinnitus had a meaningful reduction in tinnitus severity with Lenire after 6-weeks when 6-weeks of audio-only therapy had minimal impact⁴

83% of 500+ participants across three successful clinical trials would recommend Lenire.^{1,2,3,4}

Zero serious adverse side effects related to Lenire were reported, validating the safety of the device.

One bimodal neuromodulation tinnitus treatment device granted approval by the FDA following a controlled clinical trial – Lenire.

References

¹Darcy et al, BMJ Open 2017;7:e018465

²Conlon et al., JMIR Res Protoc 2019;9(9):e13176

³Conlon et al., Sci Translational Medicine. 12, eabb2830 (202)

⁴Boedts, Michael, et al. Nature communications 15.1 (2024): 6806.

⁵McMahan, Emily E., and Hubert H. Lim. medRxiv (2024): 2024-08.