

Type	Safety	Efficacy
		
Device (bimodal stimulation)	Rigorous evidence of safety, or only small risks/minor harms	Clear evidence that it is effective compared to no treatment

In detail:

About Lenire	Lenire “works to retrain neurons in the brain to reduce its attention and sensitivity to the tinnitus sound.” ¹
What is Lenire®	Lenire® is a medical device that combines sound therapy with mild electrical stimulation of the tongue. It is typically used for 60 minutes per day over a minimum of 12 weeks “Lenire® delivers mild electrical pulses to the tongue combined with sound played through headphones”. ²
How does it work?	● Sound therapy – customised audio is delivered through headphones. ● Tongue stimulation – mild electrical pulses are applied via a mouthpiece. ● Combined effect – designed to encourage changes in how the brain processes tinnitus.
Side effects & risks	● Around one third of participants in clinical trials reported a temporary worsening of tinnitus symptoms. In most cases, this resolved by the end of the study. ● Not everyone benefits from treatment ● Durability beyond 12 months after finishing treatment is not yet well established for all groups.

Tinnitus UK try very hard to make sure our information is right, but this information should not be taken as medical advice. You should always check with your doctor before trying any tinnitus treatment.

What does the research say?	In clinical trials: ● 95% of treatment-compliant participants reported an improvement in Tinnitus Handicap Inventory (THI) scores after 12 weeks.^{3,4} ● 84% reported improvement in Tinnitus Functional Index (TFI) scores ⁴ ● Large trials (TENT-A1, TENT-A2) reported clinically meaningful average reductions in Tinnitus Handicap Inventory (THI) and Tinnitus Functional Index (TFI) during treatment. Benefits persisted for some participants at follow-up.⁴ ● A one-arm controlled pivotal study (TENT-A3) compared 6-weeks sound-only then 6-weeks bimodal in the same participants. In those with moderate or worse tinnitus at baseline, bimodal showed higher responder rates than sound-only. No device-related serious adverse events were reported.^{6,7} ● Real-world clinic cohorts (including a UK/Europe network and US clinics) report improvements broadly consistent with trials ^{1,2,5,7}
Access and regulation	● UK & Europe: CE-marked medical device available through private clinics.⁵ ● USA: De Novo classification granted by the FDA creating a new Class II category for combined acoustic and electrical stimulation devices for tinnitus (brand availability through trained providers).⁷

Lenire is not routinely available on the NHS. Clinics set their own fees, which may include assessment, device hire/purchase, and follow-up.

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Further information

The Tinnitus UK Support Team can answer your questions about tinnitus and related treatments:

Telephone: **0800 018 0527**

Web chat: **tinnitus.org.uk**

Email: **helpline@tinnitus.org.uk**

Text/SMS: **07537 416841**

We also provide a free online programme, Take on Tinnitus, at **takeontinnitus.co.uk**.

Feedback

We welcome feedback on all our information.

You can pass your comments to our Communications Team by calling us on **0114 250 9933**, emailing **communications@tinnitus.org.uk** or by writing to us at the address below.

Document information

Author	IAG Manager
Version	3.1
Issue date	September 2025
Review date	September 2028
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Registered charity no: 1011145
Registered in England
Company limited by guarantee no: 2709302

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