

FDA approves first drug to help tame cluster headaches

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(HealthDay)— The U.S. Food and Drug Administration on Tuesday

gave the nod to Emgality, an injected medication that's the first to cut the frequency of cluster headaches.

Episodic [cluster headaches](#) are "an extremely painful and often debilitating condition," the FDA's Dr. Eric Bastings noted in an agency news release. He's deputy director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research.

Cluster headaches occur in quick sequence, "often at the same time(s) of the day, for several weeks to months," the agency said.

Attacks typically hit patients multiple times each day and can last anywhere from 15 minutes to three hours.

"The headaches are accompanied by symptoms that may include: bloodshot eyes, excessive tearing of the eyes, drooping of the eyelids, [runny nose](#) and/or nasal congestion and facial sweating," the FDA added.

However, Emgality (galcanezumab-gnlm) appears to be the first drug to help ease patients' misery.

In a three-week clinical trial involving 106 patients, patients who took the drug had an average of almost nine fewer weekly cluster headaches, compared to about five fewer attacks among people who got a "dummy" placebo self-injection.

Dr. Noah Rosen directs Northwell Health's Headache Center in Great Neck, N.Y. While not involved in the the clinical trial, he serves on a cluster [headache](#) advisory board.

Rosen agreed that "there are very few [treatment options](#) for patients with cluster headache—a sad situation for what is commonly accepted as one of the most painful head pain conditions a person can suffer."

He explained that Emgality is one "of a new class of antibodies targeting part of the inflammatory process involved in select headache disorders including migraine and cluster headaches."

The drug appears to be a more targeted and well-tolerated means of cutting down on [cluster](#) headache frequency, Rosen said.

The FDA noted that some patients may develop a "hypersensitivity" to Emgality that can include a rash, hives and labored breathing.

"If a serious hypersensitivity reaction occurs, treatment should be discontinued," the agency said. "Hypersensitivity reactions could occur days after administration and may be prolonged."

Emgality was first approved by the FDA in September 2018 for the treatment of migraines.

More information: There's more on cluster headaches at the [American Migraine Foundation](#).

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