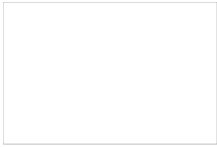


Migraine News: FDA Approves New Nasal Spray for Migraine Treatment



NERVOTONIN

Migraine is a neurological condition that usually causes painful attacks of headache accompanied by additional symptoms such as sensitivity to light, sound, smell or touch. Migraine is not just a cause of "really bad headaches" but a neurological condition that can cause a wide range of symptoms. Although it is often characterized by severe, debilitating headaches, additional symptoms may include nausea, vomiting, numbness or tingling, and sensitivity to light and sound.

The disease often runs in families and can affect people of any age. It occurs more often in women than in men.

The most common categories of migraine headaches (or attacks) are episodic and chronic, and then non-aura and with aura. Migraines are estimated to affect more than 10% of people worldwide, and women are about three times more likely to suffer from them than men. Most migraine attacks last about 4 hours. If left untreated or unresponsive to treatment, they can last anywhere from 72 hours to a week.

The Migraine Foundation of America says that 39 million Americans and 1 billions people worldwide live with migraines. Therefore, there is great news for such patients. Because in 2023 March 10, The FDA, otherwise known as the Food and Drug Administration, approved a nasal spray from Pfizer for the treatment of migraines that is different from other nasal products on the market for severe headaches. The drug has been approved for the treatment of acute migraine with or without aura in adults. An aura refers to any neurological disorder that occurs immediately before or during the development of a migraine.

A fast-acting drug called zavegepant, which will be marketed as Zavzpret, was better than a placebo at reducing pain and the most troublesome symptoms for patients, according to clinical trial results published in the journal Lancet Neurology. Study participants who took the drug were more likely to report being able to return to normal life 30 minutes to two hours after taking it.

However, the benefit was not significant for every patient. The study tracked the experiences of 1,269 patients, half on the drug and half on a placebo, focusing on how they felt two hours after taking either substance. According to the study, about 24 percent of those who took the medicine indicated that they did not feel pain, and about 15 percent of those who took the placebo.

The medicine is in the form of a nasal spray. And since migraines are often accompanied by nausea, swallowing a pill can be unpleasant. He also said that the drug has few side effects, such as drowsiness, that have been reported with other products. Many have been waiting for this drug to come out because doctors believe that it is a really useful drug for treating migraines.

One of the added benefits of the drug is that it is safe for patients who have had a heart attack or stroke.

The company that manufactures the drug said that the drug will be available in pharmacies in July, but has not yet disclosed the estimated prices of the new spray. The price is expected to be similar to other FDA-approved migraine medications in the same class.

Calling the FDA approval a "significant breakthrough." The drug is described as the first and only migraine nasal spray using a migraine inhibitor that tries to block the release of proteins called calcitonin gene-related peptides. Some other nasal products use triptans, which are drugs that target serotonin receptors, but are generally not recommended for people with vascular disease.

One associate professor of neurology, who treats migraine patients, said the new drug builds on a discovery about the role of calcitonin gene-related peptides that has been in development for decades. He thinks this discovery was really groundbreaking in helping us better understand what happens when someone has a migraine attack.

Although this class of drugs comes in tablet form, nasal sprays are absorbed more quickly, which is another advantage of the new drug treatment. Doctors hope this will help them help more people.

The main study of the drug also measured freedom from the most distressing symptoms in test participants two hours after taking the drug. Forty percent of those who took it reported improvement. Among those taking the placebo, the result was 31 percent.

Some side effects were reported by study participants. About a fifth of those taking the medication reported an altered sense of taste. Others experienced nasal discomfort and nausea. The authors of the study concluded that "further testing is needed to determine long-term safety and consistency of attack effects."

In a study published in The Lancet Neurology, about 24% of people who took a single 10-milligram dose of Zavzpret reported no pain after two hours, compared with 15% of a group that received a nasal spray without any active ingredients. This is a difference that was statistically significant. It is also important that for many patients the relief lasts up to 48 hours. The main side effect reported in the study was an altered sense of taste, which affected about 1 in 5 people who took the drug. Other side effects were an unpleasant sensation in the nose and nausea.

From 2020 October month. until 2021 August. about 1,400 people participated in the tests. For most migraineurs, one of the most important features of choosing an acute treatment is how quickly the medication works.

This nasal spray with rapid drug absorption, Zavzpret offers an alternative treatment for people who need pain relief or who cannot take oral medication due to nausea or vomiting, so that they can quickly return to their normal lives.

Zavegepant (brand name: Zavzpret) is the first of the migraine treatments known as calcitonin gene-related peptide receptor (CGRP) antagonists to be approved as a nasal spray. Until now, this type of medicine was only available in oral and injectable forms. It works by blocking peptide receptors that cause the inflammation that often accompanies migraines. The drug was approved to treat acute migraine with or without aura, which is a severe headache accompanied by uncomfortable symptoms such as dizziness, ringing in the ears, zigzag lines in vision or sensitivity to light.

Zavzpret belongs to a class of drugs called calcitonin gene-related peptide inhibitors and will compete with other treatments and hopes to gain a competitive advantage with Zavzpret's rapid onset of action.

Many different medications are already available to treat migraines, including several types of nasal sprays. The new drug isn't the first nasal spray for migraines, and it's not just the quick, 15-minute relief that gives it an advantage over existing drugs on the market. Zavzpret is the first to block the calcitonin gene-related peptide CGRP, a protein that is released in the brain and promotes inflammation. There are many people who suffer from migraines, feel very nauseous and cannot tolerate the medication they have to swallow. Zavzpret is also an alternative for people with heart disease or other conditions that prevent them from safely using other migraine treatments.

In studies previously published by Pfizer and reviewed by the FDA, zavegepant reduced moderate to severe headaches two hours after using the spray compared to those who received a placebo nasal spray. Among those who received the spray, 24% reported pain relief after two hours, compared to 15% of those who received a placebo. For some people taking the drug, relief started as soon as 15 minutes after taking the drug.

According to one of the investigators of the zavegepant study, by using CGRP drugs, scientists have for the first time studied the pathophysiology of migraines, or what causes migraines, to understand how to reverse this process. Experts believe that blocking peptide receptors associated with the calcitonin gene in the brain reduces the inflammation associated with migraine pain.

Older migraine treatments, such as triptans, constrict blood vessels, which is one way to reduce pain in the brain. However, this narrowing is dangerous for people with heart disease, so headache sufferers could not take medication or had to take suboptimal doses to relieve migraine pain.

Although many migraine patients are treated with CGRP antagonists, many patients were unable to take pills when the headache started. Many people experience nausea and vomiting during a migraine and cannot drink anything. In addition, migraines cause gastrointestinal motility to slow down, so any oral medication is not absorbed as quickly and efficiently as usual. Nasal spray works faster and avoids such cases.

CGRP antagonists are used to prevent and treat migraines, but zavegepant is only approved for the treatment of acute migraine pain at the onset of an episode. For people who experience four or more migraines per month, doctors may prescribe injectable CGRP once a month or every three months. But for every migraine sufferer, treatment is important because "we know that the more headaches people have, the more headaches they will continue to have. Even if you have a headache once every three months, your doctor should prescribe acute pain medication to stop those headaches.

In two studies in which people with migraines did not know whether they were taking the drug or a placebo, Zavzpret was more effective at reducing migraine pain within two hours than a nasal spray without any active ingredients.

When a migraine strikes, it has a significant negative impact on a person's daily life. For my migraine patients, one of the most important attributes of choosing an acute treatment is how quickly it works. As a nasal spray with rapid drug absorption, Zavzpret offers an alternative treatment option for people who need pain relief or who cannot take oral medication due to nausea or vomiting, so that they can quickly return to their normal lives.

<https://www.nbcnews.com/health/health-news/fda-approves-new-fast-acting-nasal-spray-migraines-rcna74356>

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