



Nurtec™ ODT (rimegepant) – New drug approval

- On February 27, 2020, [Biohaven Pharmaceuticals announced](#) the FDA approval of [Nurtec ODT \(rimegepant\)](#), for the acute treatment of migraine with or without aura in adults.
 - Nurtec ODT is not indicated for the preventive treatment of migraine.
- Migraine is characterized by debilitating attacks lasting four to 72 hours with multiple symptoms, including headaches of moderate to severe pain intensity that can be associated with nausea or vomiting, and/or sensitivity to sound and sensitivity to light.
 - Nearly 40 million people in the U.S. suffer from migraine.
- Nurtec ODT is a calcitonin gene-related peptide (CGRP) receptor antagonist that works by reversibly blocking CGRP receptors, thereby inhibiting the biologic activity of the CGRP neuropeptide. The activity of CGRP is thought to play a causal role in migraine pathophysiology.
- The efficacy of Nurtec ODT for the acute treatment of migraine in adults was established in a randomized, double-blind, placebo-controlled study. Patients were randomized to 75 mg of Nurtec ODT (n = 732) or placebo (n = 734). Patients were instructed to treat a migraine of moderate to severe headache pain intensity. The primary endpoints were pain freedom and most bothersome symptom (MBS) freedom at two hours after dosing.
 - Pain freedom at 2 hours post dose was achieved in 21.2% and 10.9% of patients receiving Nurtec ODT and placebo, respectively (p < 0.001).
 - MBS freedom at 2 hours post dose was achieved in 35.1% and 26.8% of patients receiving Nurtec ODT and placebo, respectively (p = 0.001).
- A warning and precaution for Nurtec ODT is hypersensitivity reactions.
- The most common adverse reaction (≥ 1%) with Nurtec ODT use was nausea.
- The recommended dose of Nurtec ODT is 75 mg taken orally, as needed. The maximum dose in a 24-hour period is 75 mg.
 - The safety of treating more than 15 migraines in a 30-day period has not been established.
- Biohaven Pharmaceuticals plans to launch Nurtec ODT in early March 2020. Nurtec ODT will be available as a 75 mg orally disintegrating tablet.



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