

Ubrelvy[™] (ubrogepant) – New drug approval

- On December 23, 2019, the [FDA announced](#) the approval of [Allergan's Ubrelvy \(ubrogepant\)](#), for the acute treatment of migraine with or without aura in adults.
 - Ubrelvy is not indicated for the preventive treatment of migraine.
- Ubrelvy is the first orally administered calcitonin gene-related peptide receptor (CGRP) antagonist approved for the treatment of migraine attacks once they start. CGRP is a protein released during a migraine attack.
- The efficacy of Ubrelvy for the acute treatment of migraine was demonstrated in two randomized, double-blind, placebo-controlled studies in 1,439 adult patients with a history of migraine. In study 1, patients were randomized to Ubrelvy 50 mg, Ubrelvy 100 mg, or placebo. In study 2, patients were randomized to Ubrelvy 50 mg or placebo. The primary endpoints in both studies were pain freedom at 2 hours post-dose and most bothersome symptom (MBS) freedom at 2 hours post-dose. MBS freedom was defined as the absence of the self-identified MBS (ie, photophobia, phonophobia, or nausea).
 - In study 1, the percentage of responders who were pain free at 2 hours post-dose was 19.2, 21.2, and 11.8 with Ubrelvy 50 mg ($p = 0.002$ vs. placebo), Ubrelvy 100 mg ($p < 0.001$ vs. placebo), and placebo, respectively. The percentage of responders who were MBS-free at 2 hours post-dose was 38.6, 37.7, and 27.8 with Ubrelvy 50 mg, Ubrelvy 100 mg, and placebo ($p < 0.001$ for both doses vs. placebo).
 - In study 2, the percentage of responders who were pain free at 2 hours post-dose was 21.8 and 14.3 with Ubrelvy 50 mg and placebo, respectively ($p = 0.007$). The percentage of responders who were MBS-free at 2 hours post-dose was 38.9 and 27.4 with Ubrelvy 50 mg and placebo, respectively ($p < 0.001$).
- Ubrelvy is contraindicated with concomitant use with strong CYP3A4 inhibitors.
- The most common adverse reactions ($\geq 2\%$ and greater than placebo) with Ubrelvy use were nausea and somnolence.
- The recommended dose of Ubrelvy is 50 mg or 100 mg taken orally with or without food.
 - If needed, a second dose may be taken at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg.
 - The safety of treating more than 8 migraines in a 30-day period has not been established
- Allergan plans to launch Ubrelvy in the first quarter of 2020. Ubrelvy will be available as 50 mg and 100 mg tablets.