Ubrelvy (ubrogepant)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Ubrelvy
- **Generic name:** Ubrogepant
- **Pharmacologic class:** Calcitonin gene-related peptide (CGRP) receptor antagonist
- **Strength and Formulation:** 50mg, 100mg; tablets
- **Manufacturer:** Allergan
- **How supplied:** Packets—6, 8, 10, 12, 30
- **Legal Classification:** Rx

Ubrelvy


Rx Only
Fold at Notch and Tear
UBRELVY™
(ubrogepant) tablets
100 mg
1 tablet


Rx Only
Fold at Notch and Tear
UBRELVY™
(ubrogepant) tablets
50 mg
1 tablet

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Indication

- For the **acute treatment of migraine** with or without aura in adults

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Dosage and Administration

- Initially 50mg or 100mg; may give a second dose at least 2hrs after initial dose (max 200mg/day)
- **Concomitant use with moderate CYP3A4 inhibitors**: initially 50mg, avoid second dose within 24hrs
- **Concomitant use with BCRP and/or P-gp only inhibitors or weak CYP3A4 inhibitors**: initially 50mg; may give second dose after 2hrs (if needed)
- **Concomitant use with moderate or weak CYP3A4 inducers**: initially 100mg; may give second dose after 2hrs (if needed)
- **Severe hepatic (Child-Pugh Class C) or renal (CrCl 15–29mL/min) impairment**: initially 50mg; may give second dose after 2hrs (if needed)
- The safety of treating more than 8 migraines in a 30-day period has not been established

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Considerations for Special Populations

- **Pregnancy:** no adequate data to evaluate risk
- **Nursing mothers**: no data on the presence of ubrogepant in human milk
- **Pediatric**: safety and effectiveness not established
- **Geriatric:** studies did not include sufficient number of patients ≥65 years; dose selection should be cautious, usually starting at low end
- **Hepatic impairment**: dose adjustment recommended with severe impairment
- **Renal impairment**: dose adjustment recommended for severe impairment; avoid in patients with end-stage renal disease

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Contraindications

- Concomitant use of **strong CYP3A4 inhibitors** (ie, ketoconazole, itraconazole, clarithromycin)

Interactions

- See **Dosage and Administration**
- Avoid strong CYP3A4 inhibitors (**see Contraindications**)
- Potentiated by **moderate CYP3A4 inhibitors** (eg, cyclosporine, ciprofloxacin, fluconazole, fluvoxamine, grapefruit juice); adjust doses
- May be potentiated by **BCRP and/or P-gp only inhibitors** (eg, quinidine, carvedilol, eltrombopag, curcumin); adjust doses
- Antagonized by **strong CYP3A4 inducers** (eg, phenytoin, barbiturates, rifampin, St. John's Wort); avoid
- **Moderate or weak CYP3A4 inducers**: dose adjustment recommended

Adverse Reactions

- **Most common (at least 2% and greater than placebo)**: nausea, somnolence

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Mechanism of Action

- Ubrogepant is a calcitonin gene-related peptide (CGRP) receptor antagonist
- CGRP is believed to play a key role in migraine pathophysiology

Pharmacokinetics

- **Absorption**: peak plasma concentrations at approximately 1.5 hours
- **Effect of food**: time to max ubrogepant plasma concentration delayed by 2 hours and resulted in 22% reduction in Cmax with no change in AUC with high-fat meal
- **Protein binding**: 87%
- **Metabolism**: primarily by CYP3A4
- **Excretion**:
  - Elimination half-life of ubrogepant is approximately 5-7 hours
  - Excreted mostly via the biliary/fecal route, while the renal route is a minor route of elimination

Clinical Trials

- Two randomized, double-blind, placebo-controlled trials (Study 1 and Study 2)
- Study 1 randomized patients to placebo (n=559) or Ubrelvy 50mg (n=556) or 100mg (n=557) and Study 2 randomized patients to placebo (n=563) or Ubrelvy 50mg (n=562)
- Patients were instructed to treat a migraine with moderate to severe headache pain intensity
- Second dose of Ubrelvy or placebo, or patient's usual acute treatment for migraine was allowed between 2-48 hours after initial treatment for a nonresponding or recurrent migraine headache

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Clinical Trials

- Primary efficacy analyses were conducted in patients who treated a migraine with moderate to severe pain
- The efficacy of Ubrelvy was established by an effect on pain freedom at 2 hours postdose and most bothersome symptom (MBS) freedom at 2 hours postdose, compared with placebo
- **Pain freedom** defined as a reduction of moderate or severe headache pain to no pain
- **MBS freedom** defined as the absence of the self-identified MBS (ie, photophobia, phonophobia, or nausea)
- Among patients who selected an MBS, the most commonly selected was photophobia (56%), followed by phonophobia (24%), and nausea (19%)

Clinical Trials

- In both studies, the percentage of patients achieving headache pain freedom and MBS freedom 2 hours postdose was significantly greater among patients treated with Ubrelvy compared with those who received placebo

- Incidence of photophobia and phonophobia was reduced following administration of Ubrelvy as compared with placebo

Clinical Trials

- **Study 1**
  - Pain free at 2 hours (% responders): Ubrelvy 50mg: 19.2%; Ubrelvy 100mg: 21.2%; placebo: 11.8%
  - MBS free at 2 hours (% responders): Ubrelvy 50mg: 38.6%; Ubrelvy 100mg: 37.7%; placebo: 27.8%
- **Study 2**
  - Pain free at 2 hours (% responders): Ubrelvy 50mg: 21.8%; placebo: 14.3%
  - MBS free at 2 hours (% responders): Ubrelvy 50mg: 38.9%; placebo: 27.4%

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/ubrelvy/