# Important Updates to the Prescribing Information for UBRELVY® (ubrogepant) tablets[1]

On February 17, 2023, the Prescribing Information and Patient Information for UBRELVY® (ubrogepant) was updated to add a Contraindication and a new Warning and Precaution for Hypersensitivity Reactions.

The relevant sections of the Prescribing Information read as follows:

## 4 CONTRAINDICATIONS

UBRELVY is contraindicated:

- In patients with a history of serious hypersensitivity to ubrogepant or any component of UBRELVY. Reactions have included anaphylaxis, dyspnea, and facial or throat edema.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, dyspnea, facial or throat edema, rash, urticaria, and pruritus, have been reported with use of UBRELVY. Hypersensitivity reactions can occur minutes, hours, or days after administration. Most reactions occurred within hours after dosing and were not serious, and some reactions led to discontinuation. If a serious or severe hypersensitivity reaction occurs, discontinue UBRELVY and institute appropriate therapy.

## 17 PATIENT COUNSELING INFORMATION

Hypersensitivity Reactions

Inform patients about the signs and symptoms of hypersensitivity reactions and that these reactions can occur with UBRELVY. Advise patients to discontinue UBRELVY and seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions.

**This is not a complete list of all the changes made to the Prescribing Information and Patient Information for UBRELVY. Please refer to the full Prescribing Information and Patient Information for additional safety information.**

**Please see accompanying full Prescribing Information or visit www.rxabbvie.com/pdf/ubrelvy_pi.pdf.**

## INDICATION

UBRELVY® (ubrogepant) is indicated for the acute treatment of migraine with or without aura in adults. UBRELVY is not indicated for the preventive treatment of migraine.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

**Drug Interactions:** UBRELVY is contraindicated with concomitant use of strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin).

**Hypersensitivity Reactions:** UBRELVY is contraindicated in patients with a history of serious hypersensitivity to ubrogepant or any ingredient of the product. Cases, including anaphylaxis, dyspnea, facial or throat edema, rash, urticaria, and pruritus, have been reported. Hypersensitivity reactions can occur minutes, hours, or days after administration. Most reactions were not serious, and some led to discontinuation. If a serious or severe reaction occurs, discontinue UBRELVY and institute appropriate therapy.

### ADVERSE REACTIONS

The most common adverse reactions were nausea (4% vs 2% placebo) and somnolence (3% vs 1% placebo).

### DRUG INTERACTIONS

- Strong CYP3A4 Inducers: Should be avoided as concomitant use will result in reduction of ubrogepant exposure.
- Dose modifications are recommended when using the following:
  - Moderate or weak CYP3A4 inhibitors and inducers
  - BCRP and/or P-gp only inhibitors

### DOSAGE AND ADMINISTRATION

- The recommended dose is 50 mg or 100 mg taken orally, as needed.
- If needed, a second dose may be administered 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.
- Severe hepatic or severe renal impairment: Recommended dose is 50 mg; if needed, a second 50 mg dose may be taken at least 2 hours after the initial dose.
- Avoid use in patients with end-stage renal disease.

**Please see accompanying full Prescribing Information or visit www.rxabbvie.com/pdf/ubrelvy_pi.pdf.**



**Reference: 1.** UBRELVY [package insert]. Madison, NJ: Allergan USA, Inc.