

Patient Information
UBRELVY® (you-brel-vee)
(ubrogepant)
tablets, for oral use

What is UBRELVY?

UBRELVY is a prescription medicine used for the acute treatment of migraine attacks with or without aura in adults. UBRELVY is not used to prevent migraine headaches. It is not known if UBRELVY is safe and effective in children.

Who should not use UBRELVY?

Do not take UBRELVY if you are

- taking medicines known as a strong CYP3A4 inhibitor, such as ketoconazole, clarithromycin, or itraconazole. Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take UBRELVY with other medicines.
- allergic to ubrogepant or any of the ingredients in UBRELVY. See the end of this Medication Guide for a complete list of ingredients in UBRELVY.

Before you take UBRELVY tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if UBRELVY will harm your unborn baby.
 - Pregnancy Registry: There is a pregnancy registry for women who take UBRELVY. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider or call 1-833-277-0206 to enroll in this registry. You can also visit <http://empresspregnancyregistry.com>.
- are breastfeeding or plan to breastfeed. It is not known if UBRELVY passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take any of the following, as your healthcare provider may need to change the dose of UBRELVY:

- | | | | | |
|--------------|----------------|-----------------|-------------------|---------------|
| • verapamil | • cyclosporine | • ciprofloxacin | • fluconazole | • fluvoxamine |
| • phenytoin | • barbiturates | • rifampin | • St. John's Wort | • quinidine |
| • carvedilol | • eltrombopag | • curcumin | | |

These are not all of the medicines that could affect how UBRELVY works. Your healthcare provider can tell you if it is safe to take UBRELVY with other medicines.

Keep a list of medicines you take to show to your healthcare provider or pharmacist when you get a new medicine.

How should I take UBRELVY?

- Take UBRELVY exactly as your healthcare provider tells you to take it.
- Take UBRELVY with or without food.
- Most patients can take a second tablet 2 hours after the first tablet, as needed.
- You should not take a second tablet within 24 hours if you consume grapefruit or grapefruit juice or are taking medications that may include:
 - verapamil
 - cyclosporine
 - ciprofloxacin
 - fluconazole
 - fluvoxamine
- It is not known if it is safe to take UBRELVY for more than 8 migraine headaches in 30 days.
- You should write down when you have headaches and when you take UBRELVY so you can talk to your healthcare provider about how UBRELVY is working for you.
- If you take too much UBRELVY, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of UBRELVY?**UBRELVY may cause serious side effects, including:**

- Allergic reactions. Allergic reactions can happen after you take UBRELVY. Most reactions happened within hours and were not serious. Some reactions may occur days after taking UBRELVY. Call your healthcare provider or get emergency help right away if you have any of the following symptoms, which may be part of an allergic reaction:
 - Swelling of the face, mouth, tongue, or throat
 - Trouble breathing

The most common side effects of UBRELVY are nausea and sleepiness.

These are not all of the possible side effects of UBRELVY. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store UBRELVY?

- Store UBRELVY at room temperature between 68°F to 77°F (20°C to 25°C).

Keep UBRELVY and all medicines out of the reach of children.

General information about the safe and effective use of UBRELVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use UBRELVY for a condition for which it was not prescribed. Do not give UBRELVY to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about UBRELVY that is written for health professionals.

What are the ingredients in UBRELVY?

Active ingredient: ubrogepant

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, mannitol, microcrystalline cellulose, polyvinylpyrrolidone vinyl acetate copolymer, sodium chloride, sodium stearyl fumarate, and vitamin E polyethylene glycol succinate.

Manufactured by: Forest Laboratories Ireland Ltd.,
Dublin, Ireland

Distributed by: AbbVie Inc.
North Chicago, IL 60064

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