

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrUBRELVY®

Ubrogепant tablets

Read this carefully before you start taking **UBRELVY** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **UBRELVY**.

What is UBRELVY used for?

UBRELVY is used to treat migraine attacks with or without aura, in adults.

How does UBRELVY work?

The active ingredient in UBRELVY is ubrogепant, which belongs to a group of medications called *gepants*. UBRELVY works by blocking the activity of a chemical called calcitonin gene-related peptide (CGRP). During a migraine attack, CGRP is released by nerve endings and binds to pain receptors in the brain. UBRELVY prevents CGRP from binding to these pain receptors to alleviate or stop migraine symptoms. UBRELVY does not affect blood vessels.

What are the ingredients in UBRELVY?

Medicinal ingredients: ubrogепant.

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

UBRELVY comes in the following dosage forms:

Oral tablet, 50 mg and 100 mg.

Do not use UBRELVY if:

- you have ever had an allergic reaction to UBRELVY or any of the ingredients in UBRELVY
- you are taking medicines known as strong CYP3A4 Inhibitors, such as ketoconazole, itraconazole, clarithromycin.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take UBRELVY. Talk about any health conditions or problems you may have, including if you:

- have a serious liver disease.
- have serious kidney disease.

Other warnings you should know about:

Driving and using machines

While using UBRELVY you may feel sleepy. Before driving a vehicle or using machinery, wait to see how you feel after taking UBRELVY.

Children and adolescents

Do not give UBRELVY to children under 18 years of age since the use of UBRELVY has not been studied in children under 18 years of age.

Oral Contraceptives

Your healthcare provider can help you choose the right oral contraceptive to use with UBRELVY. Additional methods of birth control can be used to supplement oral contraceptives.

Pregnancy and Breast-feeding

UBRELVY has not been studied in pregnant women. It is not known if UBRELVY will harm your unborn baby. Talk to your healthcare professional if you are trying to get pregnant or think you may be pregnant when taking UBRELVY. Your healthcare professional will discuss with you the potential risks of taking UBRELVY during pregnancy.

A pregnancy registry for women taking UBRELVY during pregnancy will be available soon. This registry will collect information about your health and your baby's health. If you become pregnant while taking UBRELVY, talk with your doctor about taking part in this registry.

It is not known if UBRELVY passes through breast milk. It is important to tell your healthcare professional if you are breastfeeding or plan to breastfeed. Your healthcare professional will then help you decide if you should stop breast-feeding or stop taking UBRELVY. If you breastfeed while taking UBRELVY, your healthcare professional may tell you to monitor your baby's weight and developmental milestones.

Elderly

If you are over 65 years of age, your healthcare professional may tell you to use the lowest dose of UBRELVY. Check with your healthcare professional, if you are not sure.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with UBRELVY:

- Medicines for fungal infections such as ketoconazole, itraconazole, and fluconazole.
- Antibiotics such as clarithromycin, ciprofloxacin, and rifampin.
- Medicines for high blood pressure such as verapamil, carvedilol, and bosentan.
- Medicines for seizures such as phenytoin, rufinamide, and primidone.
- Medicines known as barbiturates.
- Fluvoxamine, a medicine for depression / obsessive-compulsive disorder.
- Cimetidine, a medicine for heart burn and ulcers.
- Medicines for sleep disorders such as armodafinil and modafinil
- HIV medicines as such efavirenz and etravirine
- Quinidine, a medicine for heart disorders.
- Eltrombopag, medicine for blood disorders.
- Other medicines known as “gepants”.
- Oral contraceptives.
- Grapefruit and grapefruit juice.
- St. John’s Wort.
- Curcumin (turmeric).
- Large amounts of green tea beverages or green tea extract.

How to take UBRELVY:

- Always use UBRELVY exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

Usual dose:

- The recommended dose of UBRELVY is 50 mg or 100 mg taken orally with or without food.
- If needed, an optional second dose may be taken at least 2 hours after the initial dose.
- The maximum daily dose is 200 mg.
- It is not known if it is safe to take more than 16 doses in a 30-day period.
- Do not exceed the recommended dose prescribed by your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much UBRELVY, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using UBRELVY?

These are not all the possible side effects you may feel when taking UBRELVY. If you experience any side effects not listed here, contact your healthcare professional.

Possible side effects include the following listed below. Most of these side effects are mild to moderate. If these side effects become severe, please tell your healthcare professional.

- Nausea
- Dry Mouth
- Sleepiness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Hypersensitivity (allergic reaction): rash, hives, facial swelling, and/or shortness of breath.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store this medication between 15°C and 30°C.

Do not use this medicine after the expiry date, which is stated on the carton.

Keep out of reach and sight of children.

If you want more information about UBRELVY:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca or by calling 1-888-704-8271.

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