

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

UBREL[®]

ubrogepant tablets

This Patient Medication Information is written for the person who will be taking **UBREL[®]**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **UBREL[®]**, talk to a healthcare professional.

What UBREL[®] is used for:

UBREL[®] is used to treat migraine attacks with or without aura, in adults.

How UBREL[®] works:

The active ingredient in UBREL[®] is ubrogepant, which belongs to a group of medications called *gepants*. UBREL[®] 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. UBREL[®] prevents CGRP from binding to these pain receptors to alleviate or stop migraine symptoms. UBREL[®] does not affect blood vessels.

The ingredients in UBREL[®] are:

Medicinal ingredient: ubrogepant

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

UBREL[®] comes in the following dosage form:

Oral tablet; 50 mg and 100 mg of ubrogepant.

Do not use UBREL[®] if:

- you have ever had an allergic reaction to UBREL[®] or any of the ingredients in UBREL[®]
- 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 Breastfeeding**

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 is available for women taking UBRELVY during pregnancy. This registry collects information about your health and your baby's health. If you become pregnant while taking UBRELVY, talk with your healthcare professional about taking part in this registry. You can enroll in this registry at www.empresspregnancyregistry.ca, or by calling 1-844-467-0844.

It is important to tell your healthcare professional if you are breastfeeding or plan to breastfeed. Very small amounts of UBRELVY pass into breast milk. Your healthcare professional will help you decide the best way to feed your baby if you take UBRELVY.

- **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 migraine 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.
- Feverfew (Tanacetum parthenium)

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, regional poison control centre or Health Canada’s toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using UBRELVY:

These are not all the possible side effects you may have when taking UBRELVY. If you experience any side effects not listed here, tell 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

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this 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.			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare 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 the Patient Medication Information by visiting the Health Canada Drug Product Database 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.

This leaflet was prepared by AbbVie Corporation.

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