PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a doctor's prescription only

Ubrelvy 50 mg, tablets
Ubrelvy 100 mg, tablets

The active ingredient and its quantity:
Each tablet contains:
Ubrelvy 50 mg, tablets ubrogepant 50.0 mg/tablet (equivalent to 54.9 mg of ubrogepant free base trihydrate)
Ubrelvy 100 mg, tablets ubrogepant 100.0mg/tablet (equivalent to 109.8 mg of ubrogepant free base trihydrate)

For the list of inactive ingredients, please see section 6 "Further Information" in this leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.
This medicine is intended for use in adults above the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

UBRELVY contains the active substance ubrogepant, a calcitonin gene-related peptide (CGRP) receptor antagonist. UBRELVY is used for the acute treatment of migraine attacks with or without aura in adults.
Limitations of Use
UBRELVY is not indicated for the preventive treatment of migraine.

Therapeutic group: antimigraine preparations, calcitonin gene-related peptide (CGRP) antagonist.

2. BEFORE USING THE MEDICINE

Do not use the medicine:
- If you are sensitive (allergic) to the active substance ubrogepant or any of the other ingredients of this medicine (listed in section 6).
- if you are taking medicines known as a strong CYP3A4 inhibitors such as: ketoconazole, itraconazole, clarithromycin. See "Drug interactions".

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.

Special warnings about using this medicine:
Talk to your doctor or pharmacist before UBRELVY treatment if you:

- have liver problems
- have kidney problems

Children and adolescents
This medicine is not intended for children and adolescents below the age of 18.
There is no information regarding the safety and efficacy of using this medicine in children and adolescents below the age of 18.

Drug interactions
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, herbal medicines and supplements. Especially if you take any of the following, as your healthcare provider may need to change the dose of UBRELVY:

- medicines used to treat infections (e.g., fluconazole, ciprofloxacin, rifampin)
- medicines used to treat high blood pressure or heart conditions (e.g., verapamil, carvedilol, quinidine)
- medicines that affect your immune system (e.g., cyclosporine)
- medicines used to treat obsessive-compulsive disorder (e.g., fluvoxamine)
- medicines used to treat seizures and other neurological disorders (e.g., phenytoin, barbiturates)
- medicines used to stimulate the bone marrow (e.g., eltrombopag)
- certain herbal supplements (e.g., St. John's wort, curcumin)

These are not all 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.

Using with food and drink
Ubrelvy is taken orally with or without food.
You should not take a second tablet within 24 hours if you consume grapefruit or grapefruit juice.

Pregnancy and breast feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, discuss this with your doctor before UBRELVY treatment.

Pregnancy:
It is not known if UBRELVY will harm your unborn baby.

Breast feeding:
It is not known if UBRELVY passes into your breast milk.

Driving and using machines
UBRELVY is not expected to have any effect on the ability to drive and use machines.

Important information about some of this medicine's ingredients
Ubrelvy 50 mg contains 24.15 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.

Ubrelvy 100 mg contains 48.30 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the doctor only. The acceptable dosage is usually:

50 mg or 100 mg taken orally with or without food. If needed, a second dose may be taken at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg. 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.

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

Details on dosage in special populations

<u>Severe Hepatic or Severe Renal Impairment:</u>
Recommended dose is 50 mg; if needed, a second 50 mg dose may be taken at least 2 hours after the initial dose.

Do not exceed the recommended dose.

How to take UBRELVY

- Take the tablets with or without food
- Swallow the tablets whole with a glass of water
- There is no information regarding chewing, crushing and breaking the tablets

If you have accidentally taken a higher dose of UBRELVY
If you have taken an overdose of UBRELVY, immediately call a doctor or go to the nearest hospital emergency room.
If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you**.**

If you stop taking UBRELVY

Do not stop using UBRELVY without talking to your doctor first.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of UBRELVY may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common: may affect up to 1 in 10 people

- nausea
- fatigue
- sleepiness
- dry mouth

If a side effect has occurred, if any of the side effects worsen or if you experience a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs to the online form for reporting side effects, or by entering the link:
<u>https://sideeffects.health.gov.il</u>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appears on the carton package. The expiry date refers to the last day of that month.
- Store at below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredients, this medicine also contains:

UBRELVY 50mg :
polyvinylpyrrolidone vinyl acetate copolymer, mannitol, sodium chloride, croscarmellose sodium, microcrystalline cellulose, vitamin E polyethylene glycol succinate, sodium stearyl fumarate, colloidal silicon dioxide.

UBRELVY 100mg :
polyvinylpyrrolidone vinyl acetate copolymer, mannitol, sodium chloride, croscarmellose sodium, microcrystalline cellulose, vitamin E polyethylene glycol succinate, sodium stearyl fumarate, colloidal silicon dioxide.

What UBRELVY looks like and the contents of the package:

UBRELVY 50 mg: white to off-white, capsule-shaped, biconvex tablets debossed with “U50” on one side in unit-dose packets (each packet contains 1 tablet)

UBRELVY 100 mg: as white to off-white, capsule-shaped, biconvex tablets debossed with “U100” on one side in unit-dose packets (each packet contains 1 tablet)

- Box of 6, 8, 10, 12, 16, 30 packets

Not all pack sizes may be marketed.

- License holder and its address: AbbVie Biopharmaceuticals Ltd., 4 Hacharash Street, Hod Hasharon, Israel
- Manufacturer name and its address: Forest Laboratories Ireland Ltd., Dublin, Ireland
- Revised in July 2022.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  UBRELVY 50 mg: 169-77-37037-99
  UBRELVY 100 mg: 169-78-37038-99