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 100.0 mg/tablet (equivalent to 109.8 mg of ubrogepant free base trihydrate)

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

See also "Important information about some of this medicine's ingredients" in section 2.

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/ for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment/ medical condition 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 to any of the other ingredients of this medicine (listed in section 6). Serious allergic reactions may include life-threatening allergic reaction (anaphylaxis), difficulty breathing, and swelling of the face, mouth, tongue, or throat. See section "Special warnings about using this medicine" and section 4 "Side Effects".
- if you are taking medicines known as a strong CYP3A4 inhibitors such as: ketoconazole, itraconazole, clarithromycin. See section "Drug interactions".

Ask your doctor if you are not sure if you are taking any of these medicines. Your doctor can tell you if it is safe to take UBRELVY with other medicines.

Special warnings about using this medicine

Before starting treatment with UBRELVY, tell your doctor if you:

- have liver problems
- have kidney problems

Allergic reactions (hypersensitivity reactions): Allergic reactions can happen after taking UBRELVY. Most reactions occurred within hours and were not serious. Some reactions may occur days after taking UBRELVY. Serious allergic reactions may include life threatening allergic reaction (anaphylaxis), swelling of the face, mouth, tongue or throat, difficulty breathing, rash, itching, raised and itchy red bumps on the skin (urticaria). **Refer immediately to the doctor or for medical assistance** if any of the above-mentioned reactions occur. See section 4 "side effects".

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

If you are taking, or have recently taken, other medicines, including medicines obtained without a prescription and nutritional supplements, tell the attending doctor or pharmacist. Especially if you take any of the following medicines, as your doctor 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 doctor can tell you if it is safe to take UBRELVY with other medicines.

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

Use 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, breast-feeding and fertility

Pregnancy

Before taking UBRELVY, tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. It is not known if UBRELVY will harm your unborn baby.

Breast-feeding

Before taking UBRELVY, tell your doctor if you are breast-feeding or plan to breast-feed. 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 doctor 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

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.

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 or splitting the tablets

If you have accidentally taken a higher dose of UBRELVY

If you have taken an overdose or if a child has accidently swallowed some medicine, refer immediately to a doctor or go to the nearest hospital emergency room and bring the package of the medicine with you.

If you stop taking UBRELVY

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

Do not take medicines in the dark! Check the label and dose each time 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.

Serious side effects:

- Allergic reactions (hypersensitivity reactions) – can happen after you take UBRELVY. Most reactions occurred within hours and were not serious. Some reactions may occur days after taking UBRELVY. **Refer to your doctor 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
  - Difficulty breathing
  - Rash, itching, raised and itchy red bumps on the skin (urticaria)
  - Life threatening allergic reaction (anaphylaxis)

Common side effects: may affect up to 1 in 10 users

- 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:

https://sideeffects.health.gov.il

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) that appears on the carton package. The expiry date refers to the last day of that month.
- Store below 25°C.

6. FURTHER INFORMATION

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

UBRELVY 50 mg:

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

UBRELVY 100 mg:

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.

UBRELVY 100 mg: as white to off-white, capsule-shaped, biconvex tablets debossed with "U100" on one side.

UBRELVY 50 mg and UBRELVY 100 mg are supplied in a carton pack that contains sachets (each sachet contains 1 tablet).

Pack sizes: Packs of 6, 8, 10, 12, 16, 30 tablets.

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 March 2023 according to MOH guidelines.
- **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

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