



(Updated 2/6/22)

UBRELVY™ (UBROGEPANT)

UBRELVY, also known as ubrogepant, is a prescription medication by Allergan for the abortive treatment of migraine in adults. UBRELVY was FDA approved December 23, 2020 and became available in doctors' offices in February 2020. This page is designed to answer some of the frequently asked questions about UBRELVY, as well as provide some helpful resources. UBRELVY comes as individually wrapped 50mg or 100mg tablets.

IMPORTANT NUMBERS & WEBSITES (USA)

- Allergan Customer Service Telephone: 800-678-1605
- Ubrelyv Customer Service Telephone: 844-482-7358
- Ubrelyv Co-Pay Program: Text "UBRELVY" to 48764
- Allergan Patient Assistance Program Telephone: 800-78-1605
- Allergan Website: www.allergan.com
- Ubrelyv Co-Pay Program Website: www.ubrelyv.com/savings
- Ubrelyv Website: www.ubrelyv.com
- Allergan Patient Assistance Programs Website: www.allergan.com/patient-assistance-programs
- Report Side Effects To: www.fda.gov/medwatch or call: 800-FDA-1088

MEDICATION INFORMATION

- 1. What format does the medication come in?**
A: Ubrelyv comes as a 50mg and 100mg white oral tablet.
- 2. How much does Ubrelyv cost?**
A: The list price of Ubrelyv is \$85 per tablet and it comes as a pack of 10 tablets for a total cost of \$850.
- 3. How do I store/handle Ubrelyv?**
A: Ubrelyv should be stored between 20°C and 25°C (68°F and 77°F): excursions permitted between 15°C and 30°C (59°F and 86°F).
- 4. How often may I take Ubrelyv?**
A: Please see the medication guide for details about dosing. The maximum dose of Ubrelyv for healthy patients is two doses of 100mg in a 24 hour period. The safety of treating more than 8 migraine days in a 30 day period has not been established.
- 5. How long does it take for Ubrelyv to start working?**
A: In clinical studies some patients experienced pain relief as well as relief from their other most bothersome symptom within 2 hours.
- 6. How long before I know if this medication is going to help me?**
A: If your doctor has approved you to take two doses of Ubrelyv for a migraine attack then the second dose can be taken 2 hours after the first dose. If the second dose does not help Ubrelyv cannot be taken again within the 24 hour period. Since Ubrelyv is an abortive with a half-life of 5-7 hours, you should know fairly soon if it is going to help you. However, bear in mind that migraine is complex so it may take trying Ubrelyv a few times to know for sure whether or not it will help with at least some of your migraine attacks.

7. **What is the half-life of Ubrelvy?**
A: The half-life of Ubrelvy is 5-7 hours.
8. **Will Ubrelvy help my other migraine symptoms besides pain?**
A: In clinical studies some patients experienced relief from their most bothersome other symptom besides pain within 2 hours.
9. **Do I have to get this from a specialty pharmacy or do the mainstream ones also carry it?**
A: Some doctors have samples of Ubrelvy for patients to try. Ubrelvy should be available in most regular pharmacies shortly and should not require a specialty pharmacy.
10. **What about my teenage son/daughter? Can they take this medication?**
A: Ubrelvy is currently only approved in the USA for adults 18 years and older. If a doctor prescribes it to a teenager or other minor that would be off-label and a personal decision you make with that doctor.
11. **What are the main differences between Ubrelvy and triptan medications?**
A: Triptans and Ubrelvy (a gepant) are completely different genres of migraine abortive medications. One of the biggest differences is that there are currently no cardiovascular warnings or precautions with Ubrelvy since it does not cause vasoconstriction.
12. **What are the main differences between Ubrelvy and Reyvow?**
A: Ubrelvy and Reyvow are completely different genres of medication and both are “first-in-class” migraine abortive options. Ubrelvy is a CGRP inhibitor receptor antagonist whereas Reyvow is a serotonin receptor agonist. Neither causes vasoconstriction nor have cardiovascular warnings. There are different medication contraindications for each one, and they have different side effect profiles. The efficacy profile appears to be fairly similar at this point in time.
13. **What are the main differences between Ubrelvy and the other gepants?**
A: Ubrelvy is the first gepant to be FDA approved with Nurtec coming shortly after, Qulipta approved in 2021, and zavegepant (brand name unknown) still in clinical trials. Ubrelvy is a migraine abortive and comes as a white oral tablet. Rimegepant is a migraine abortive and preventive, and comes as an oral dissolving tablet. Qulipta is an oral preventive taken every day. zavegepant is an abortive that is a nasal spray. Bear in mind that just because one gepant is not effective for you that does not necessarily mean another one will not be, and vice versa.

SIDE EFFECTS, SAFETY & CONTRAINDICATIONS

14. **What are the known side effects?**
A: The most common ones are nausea, sleepiness, and dry mouth for a small percentage of people.
15. **What do I do if I think I’m getting a side effect not listed?**
A: Contact your doctor and if the side effect is serious, ongoing, or requires medical treatment in any form then PLEASE report it to the FDA at <https://www.fda.gov/safety/medwatch/>. You can also call Allergan at 800-678-1605 to report it. Please note that when you tell your doctor they are not necessarily required to make an official report of side effects, so we encourage self-reporting to the FDA and pharmaceutical company.
16. **Can I take Ubrelvy with triptans, Reyvow and/or the CGRP preventives?**
A: Right now, triptans are not listed as contraindicated with UBRELVEY. There is no data on Reyvow or the injectable CGRP inhibitors. As always, please discuss specific concerns with your doctor but realize that these medications are too new to know all the potential side effects and contraindications.
17. **Can I take this with cardiovascular or other vascular problems?**
A: UBRELVEY is not contraindicated with cardiovascular conditions. There currently are no cardiovascular warnings and precautions.

18. I am concerned that I am having a side effect from this medication. What should I do?

A: Nausea, sleepiness and dry mouth were the most commonly seen side effects in the clinical trials. If you are concerned about one of these or another unlisted side effect please contact your doctor immediately and if it lasts, is serious or requires medical treatment of any kind please report it to the FDA at <https://www.fda.gov/safety/medwatch/> as well as to Allergan at 800-678-1605. For urgent situations please go to urgent care or the ER.

19. Can I take Ubrelvy if I have renal or hepatic impairment?

A: According to the medication guide there is a dosing adjustment for people with severe renal or hepatic impairment. Ubrelvy is contraindicated with end-stage renal disease.

20. Can I take this if I am pregnant, nursing, or planning to get pregnant or nurse?

A: There is not enough data to know if Ubrelvy will harm development during pregnancy and no trials have been done with humans. However, based on animal data, Ubrelvy may cause fetal harm including embryofetal mortality and decreased body weight at birth. There is no data on the presence of Ubrelvy in human breast milk, the effects to breastfed infants, or ability to produce milk. Animal testing showed levels of Ubrelvy in breast milk comparable to peak plasma concentrations. The developmental and health benefits of breastfeeding should be considered by your healthcare provider along with the mother's clinical need for Ubrelvy and any potential adverse effects on the breastfed infant from Ubrelvy or an underlying maternal condition.

21. Can I take this if I am unable to take triptans due to their side effects?

A: Ubrelvy is not contraindicated with cardiovascular conditions which is often a reason patients cannot take triptans. If you experience other side effects from triptans that is not necessarily a reason for Ubrelvy to cause those same side effects. Ubrelvy is a "first in class" medication and a completely different genre than triptans.

22. Can I take this if I am unable to take CGRP preventives due to their side effects?

A: There was no clinical study testing concomitant use of the injectable CGRP preventives and Ubrelvy. Please talk to your doctor about this to determine if Ubrelvy is appropriate for you to take while bearing in mind the lack of data at this time. As always, with new medications there are more unknowns than knowns, and how Ubrelvy reacts in real-world use remains to be seen.

23. Can I take this if I have medication overuse headache (MOH)?

A: Ubrelvy has not been tested with MOH and is not designed to be used as a preventive or taken daily. Please talk to your doctor to determine if Ubrelvy is an appropriate option for you to try.

24. Are there any medications or substances which are contraindicated with Ubrelvy?

Strong CYP3A4 Inducers should be avoided when taking Ubrelvy as concomitant use will result in reduction of ubrogepant exposure. Concomitant use of moderate and weak CYP3A4 inducers and inhibitors, or BCRP and/or P-gp inhibitors, may require dosage modification. Please refer to section 2.2 in the [Ubrelvy medication guide](#).

INSURANCE – USA ONLY

25. What happens if my insurance requires a prior authorization (PA)?

A: Your doctor should be able to submit a prior authorization easily together with any documentation asked for.

26. I saw my doctor last week, two weeks ago, etc., and have not heard back. Now what?

A: You are your own best advocate. It's important to follow up with your doctor's office regularly to track the progress of the medication request and ensure they submitted the forms and information to get it approved.

27. What happens if my insurance denies Ubrelvy?

A: Your doctor should be working with your insurance to appeal any denial. Your insurance may require a Prior Authorization, letter of medical necessity, information about your medical history and more. It is possible to appeal multiple times when insurance denies coverage. Some doctors' offices are reluctant to file appeals because it is time consuming; sometimes you can help this process by being a "squeaky wheel," but other times you may need to submit the appeal(s) yourself. We have a document in our Files giving information on how to file an appeal yourself when necessary.

<https://www.facebook.com/download/preview/437511106724266>

28. How long will it take for my insurance to cover Ubrelvy?

A: There is no set time for this. We expect some insurance companies to cover it quickly, while others may take a little while, and still others will fight it as long as they can! Many will require a prior authorization and/or a letter of medical necessity and some will need several appeals. We suggest staying on top of the approval process, so your "paperwork" doesn't get lost in the mix. Often it is the "squeaky wheel" that gets the oil!

UBRELVY ACCESS – USA ONLY

29. Is there a copay program for Ubrelvy?

A: There is a \$10 copay program available for patients 18 years or older with commercial insurance. You can apply for that by texting "UBRELVY" to 48764 or by registering online at: www.ubrelvy.com/savings. This program covers up to 10 tablets per month for \$10. Patients with government-funded health insurance such as Medicare, Medicaid and TriCare are not eligible for this program. This program is not available for cash-paying patients or those with HMOs that cover the full cost of their medication. This offer is valid for up to 12 prescription fills through December 31, 2020. Offer applies only to prescriptions filled before the program expires on December 31, 2020. There are some caveats and conditions to the copay program that are important to be aware of:

(a) You need to activate the copay card BEFORE going to the pharmacy the first time

(b) For the first use of the copay card the medication does NOT need to be on formulary in order for the card to work. All that needs to happen is for a PA to be submitted/requested. If the pharmacy sees that the copay card is being denied they can do a "CODE 3 OVERRIDE" for the first time only.

(c) After the first time use, it is each person's responsibility to follow through on any insurance request for a prior authorization (PA) or to appeal any denial and get a formulary exception in order for the Copay card to work.

(d) The only exception to the above is if the pharmacy gets an "NDC BLOCK" code when they try to process the medication through the insurance and copay card. In this specific situation the copay card can be used multiple times without the insurance company having it on formulary.

30. I have government-funded insurance; am I eligible for any programs to access Ubrelvy?

A: Due to FDA rules copay programs are not available to patients with government-funded health insurance such as Medicare, Medicaid and TriCare. Allergan does have a Patient Assistance Program available for many of their medications, however Ubrelvy is currently not listed. We encourage you to go to their website: <https://www.allergan.com/patient-assistance-programs> to watch for updates or call the Ubrelvy telephone hotline 844-482-7358 for more information.

31. Is there a free trial for Ubrelvy?

A: There is no official free trial program for Ubrelvy, but many doctors have free samples available.

32. Are there any USA doctors close to me who are prescribing Ubrelvy?

A: We do not have information about specific doctor's prescribing practices, however if you are able to see a certified headache specialist it may be easier to access the medication. You can **CLICK HERE to see a list of every certified headache doctor** in the USA as well as some that are recommended by patients. If you are not able to see a certified headache specialist, which is true for most migraine patients, then we suggest finding a neurologist who is open to learning about these new medications.

HOPE FOR MIGRAINE GROUP INFORMATION

If you are not already a member you are welcome to join the **Hope for Migraine** group as well as our partner, **Migraine Meanderings**, for all things migraine.

RESOURCES

www.ubrelvylive.com

www.ubrelvy.com

<https://www.allergan.com/News/Details/2019/12/Allergan%20Receives%20US%20FDA%20Approval%20for%20UBRELVY%20for%20the%20Acute%20Treatment%20of%20Migraine%20with%20or%20without%20Au>

<https://www.drugs.com/ubrelvy.html>

https://media.allergan.com/products/Ubrelvy_pi.pdf