Nurtec ODT FAQs



(Updated 2/6/22)

NURTEC[™] ODT (rimegepant)

Nurtec, also known as rimegepant, is a prescription medication by Biohaven for the abortive treatment of migraine in adults as well as for preventive treatment. It is a CGRP receptor antagonist. Nurtec was FDA approved February 27, 2020 and is now available by prescription at local pharmacies across the country. This page is designed to answer some of the frequently asked questions about Nurtec, as well as provide some helpful resources. Nurtec is available as a 75mg orally dissolving tablet.

IMPORTANT NUMBERS & WEBSITES (USA)

Nurtec Customer Service Telephone: 833-468-7832

• Nurtec Co-Pay Program: text NSAVE to 26789

Nurtec Patient Assistance Program: 866-473-0088

Nurtec Website: https://www.nurtec.com

• PPARx Website: www.pparx.org Tel: 888-477-2669

Report Side Effects To: www.fda.gov/medwatch or call: 800-FDA-1088

MEDICATION INFORMATION

1. What format does the medication come in?

A: Nurtec comes in an orally dissolving 75mg tablet. Each package has eight tablets.

2. How do I store/handle Nurtec?

A: Nurtec should be stored at 20° C to 25° C (68° F to 77° F); excursions permitted between 15° C to 30° C (59° F to 86° F).

3. How often may I take Nurtec?

A: The recommended dose of Nurtec for acute treatment of migraine is 75mg up to once daily as needed. The maximum dose in one day is 75mg. The safety of treating more than 15 migraine attacks in a 30-day period has not been established. The recommended dose of Nurtec for preventive treatment of migraine is 75mg taken on alternate days.

4. How long does it take for Nurtec to start working?

A: A single dose of Nurtec can provide fast pain relief and return patients to normal function within one hour – for some patients, relief is experienced within minutes. Nurtec can deliver sustained efficacy for up to 48 hours for many patients. For preventive treatment, sometimes medications can take up to 3 months to show efficacy, although many patients experience relief sooner.

5. What is the half-life of Nurtec?

A: The half-life of Nurtec is approximately 11 hours in healthy patients.

6. Will Nurtec help my other migraine symptoms besides pain for acute treatment?

A: In clinical trials Nurtec helped relieve the "most bothersome symptom" besides pain such as nausea, vomiting, photosensitivity, etc. within two hours post-dose.

7. Do I have to get this from a specialty pharmacy or do the mainstream ones also carry it?

A: Nurtec should be available in all retail pharmacies.

8. Is Nurtec a controlled substance?

A: Nurtec is not a scheduled or controlled substance.

9. What about my teenage son/daughter? Can they take this medication?

A: Nurtec 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. We are not aware of any current Nurtec trials for minors although this may change at any time.

10. What are the main differences between Nurtec and triptan medications?

A: Triptans and Nurtec (a gepant) are completely different genres of migraine abortive medications. One of the biggest differences is that there are there are currently no cardiovascular warnings or precautions with Nurtec since it does not cause vasoconstriction. In addition, Nurtec is also FDA approved to treatment migraine as a preventive.

11. What are the main differences between Nurtec and Reyvow?

A: Nurtec and Reyvow are completely different genres of medication although both are abortive options. Nurtec, like 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. Another difference is that Nurtec is also approved to treat migraine as a preventive.

12. What are the main differences between Nurtec and the other gepants?

A: Nurtec is the second gepant to be FDA approved with Ubrelvy approved late 2019 and available on the market in February 2020, and Qulipta approved late 2021. Nurtec is a migraine abortive and preventive, and it comes as an oral dissolving white oral tablet. Ubrelvy is a migraine abortive that comes as an oral tablet. Qulipta is an oral preventive. Bear in mind that just because one gepant is not effective for you, or because a CGRP inhibitor injectable doesn't work, that does not necessarily mean this medication will not work for you.

13. How do I take it as a preventive versus as an abortive?

The Nurtec website contains full prescribing information about this medication. It is FDA approved for preventive treatment with a dosage of one tablet on alternate days.

SAFETY, SIDE EFFECTS & CONTRAINDICATIONS

14. What are the known side effects?

A: The most common side effects as seen in the clinical trials are: nausea (2%), urinary tract infection, and hypersensitivity reactions (<1%).

15. What do I do if I think I'm getting a serious side effect, or a side effect not listed?

A: If you are concerned about a side effect please contact your doctor immediately. For urgent situations please go to urgent care of the ER. We also strongly recommend that any side effects needing medical care, a new medication, or cessation of Nurtec be reported directly to Biohaven as well as the FDA at: https://www.fda.gov/safety/medwatch/. Please also let us know about side effects!

16. Can I take Nurtec with triptans and/or the CGRP preventives?

A: Nurtec was not specifically tested with the triptans in the clinical trials so it is unknown about the safety of coadministration. There was one very small trial involving Aimovig and Nurtec that was recently published. This study concluded that Nurtec may be effective for acute treatment during concomitant erenumab preventive administration. However, it also stated that the mechanism underlying the benefits of concomitant use of a small molecule CGRP receptor antagonist and an anti-CGRP receptor antibody is unknown and requires further study. Please discuss concomitant medication use with your doctor for medical advice and safety.

17. Can I take this with cardiovascular or other vascular problems?

A: Nurtec does not cause vasoconstriction, and in clinical trials patients with stable cardiovascular disease and risk factors were included. However, please talk to your doctor about your specific condition and safety. We are unable to offer medical advice here.

18. Can I take Nurtec if I have renal or hepatic impairment?

Avoid use of Nurtec if you have severe hepatic impairment or end-stage renal disease. No dosage adjustment of Nurtec is required in patients with mild or moderate hepatic impairment. No dosage adjustment of Nurtec is required in patients with mild, moderate or severe renal impairment. Nurtec has not been studied in patients on dialysis.

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

A: There is no adequate data on the developmental risk associated with the use of Nurtec in pregnant women or if it passes into the breast milk while lactating. In some animal studies, oral administration of Nurtec during organogenesis resulted in adverse effects on development. Please consult with your doctor for medical advice.

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

A: Please consult with your doctor for medical advice about the safety of Nurtec in your specific situation. Nurtec is part of the "gepant" class of medication which according to the medication guide does not show vasoconstriction like the triptans.

21. 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 Nurtec. Please talk to your doctor about this to determine if Nurtec 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 Nurtec reacts in real-world use remains to be seen.

22. Are there any medications or substances which are contraindicated with Nurtec?

Concomitant administration of Nurtec with strong inhibitors of CYP3A4 results in a significant increase in medication exposure and should be avoided. Concomitant administration with moderate inhibitors may result in increased medication exposure and a second dose of Nurtec should be avoided within 48 hours in this situation. Concomitant administration with strong or moderate inducers of CYP3A can result in significant reduction in medication exposure which may lead to loss of efficacy; concomitant administration of these inhibitors should be avoided. Concomitant administration with inhibitors of P-gp or BCRP may result in a significant increase in medication exposure and should be avoided.

INSURANCE - USA ONLY

23. 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. One of the questions likely to be asked is whether you have already tried specific triptans. If you are eligible to use the copay card your pharmacist should be able to process the script before the PA process is completed, however they may need to enter an "03" override code.

24. 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 information needed to get it approved. You can also call your insurance company directly to help expedite the process.

25. What happens if my insurance denies Nurtec?

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

26. How long will it take for my insurance to cover Nurtec?

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!

Nurtec ACCESSIBILITY - USA ONLY

27. Is there a copay card or savings program for Nurtec?

A: There is a copay program that provides Nurtec for as low as \$0 copay for eligible patients with commercial insurance. The copay cards are available at doctors' offices and some pharmacies as well as via text. You can text NSAVE to 26789 to download and activate a card. The terms and conditions for this program can be found by **CLICKING HERE**. Your pharmacist may need to enter an "03" override code if a PA is required and hasn't yet been completed.

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

A: Due to FDA rules copay programs are not available to patients with government-funded health insurance such as Medicare, Medicaid and TriCare. However, Biohaven has a Patient Assistance Program (PAP) which you may be eligible for. You can **download and print the PAP form here**.

29. What is the Patient Assistance Program (PAP)?

The Biohaven PAP is designed to help make Nurtec available to those patients who otherwise may not be able to access it – especially for those who do not have commercial insurance and who can't use the Copay Card. Eligibility includes: legal USA resident, gross household income less than or equal to 300% of the Federal Poverty Level, uninsured or "functionally" uninsured (e.g. no coverage for the medication), provide a social security number or other evidence of income. You can <u>DOWNLOAD THE PAP FORM HERE</u> or call 866-473-0088.

30. What is the Partnership for Prescription Assistance?

Patients who aren't eligible for the savings program can reach out to the Partnership for Prescription Assistance (PPARx)®. This is an independent organization that provides a single point of access to numerous patient assistance programs and healthcare resources. The program assists patients with meeting their healthcare needs for free or at a reduced cost. Resources include locating free and low-cost clinics in your area, identification of disease advocacy support programs and organizations dedicated to aiding with health insurance and access problems. PPARx does NOT provide free medicine, but rather connects individuals to healthcare support resources that may be able to assist them. Contact Information: https://www.pparx.org/ Or 1-888-4PPA-Now (1-888-477-2669). You can also contact the Patient Advocate Foundation Migraine Matters for free case management assistance at: www.patientadvocate.org/MigraineMatters.

31. Is there a free trial for Nurtec?

A: There is no official free trial program for Nurtec, but you may be able to get a 2-tablet sample from your doctor's office.

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

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 <u>CLICK HERE to see a list of every certified headache doctor</u> 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

https://www.nurtec.com/

https://www.nurtec.com/pi

https://www.biohavenpharma.com/investors/news-events/press-releases/02-27-2020

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212728s000lbl.pdf

https://n.neurology.org/content/early/2020/01/13/WNL.00000000008944?fbclid=IwAR2h7ipgYhdoIUbCdzLT

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