

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrNURTEC® ODT

Rimegepant Orally Disintegrating Tablets

Read this carefully before you start taking **NURTEC ODT** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NURTEC ODT**.

Serious Warnings and Precautions

- If an allergic reaction occurs, stop taking NURTEC ODT and contact your healthcare professional right away. Severe allergic reactions, including shortness of breath and rash, can occur days after administration.

What is NURTEC ODT used for?

NURTEC ODT is used in adults to treat an active migraine attack.

How does NURTEC ODT work?

NURTEC ODT contains the active ingredient rimegepant hemisulfate sesquihydrate and belongs to a group of medicines known as “calcitonin gene-related peptide (CGRP) antagonists”. It reduces the activity of a substance in the body called calcitonin gene-related peptide (CGRP) that causes migraine attacks.

What are the ingredients in NURTEC ODT?

Medicinal ingredient: rimegepant hemisulfate sesquihydrate.

Non-medicinal ingredients: Benzyl alcohol, eucalyptol, gelatin, limonene, maize maltodextrin, mannitol, menthol, menthone, menthyl acetate, sucralose, and vanillin.

NURTEC ODT comes in the following dosage forms:

Orally Disintegrating Tablets (ODTs): 75 mg of rimegepant (as rimegepant sulfate).

Do not use NURTEC ODT if:

- you are allergic to rimegepant, or any of the other ingredients in NURTEC ODT.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NURTEC ODT. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- have kidney problems.
- are pregnant, think you may be pregnant or are planning to have a baby. Talk to your healthcare professional before using NURTEC ODT. Your healthcare professional will decide if NURTEC ODT is right for you.
- are breast-feeding or are planning to breast-feed. Talk to your healthcare professional before using NURTEC ODT. You and your healthcare professional will decide if you will use NURTEC ODT while breast-feeding.

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 NURTEC ODT:

- itraconazole and clarithromycin (medicines used to treat fungal or bacterial infections).
- ritonavir and efavirenz (medicines to treat HIV infections).
- bosentan (a medicine used to treat high blood pressure).
- St. John's wort (a herbal remedy used to treat depression).
- phenobarbital (a medicine used to treat epilepsy).
- rifampicin (a medicine used to treat tuberculosis).
- modafinil (a medicine used to treat narcolepsy).
- fluconazole and erythromycin (medicines used to treat fungal or bacterial infections).
- diltiazem, quinidine, and verapamil (medicines used to treat an abnormal heart rhythm, chest pain (angina) or high blood pressure).
- cyclosporine (a medicine used to prevent organ rejection after an organ transplant).
- grapefruit juice.
- calcitonin gene-related peptide (CGRP) antagonists (medicines used to treat migraines).

How to take NURTEC ODT:

- NURTEC ODT is for oral use.
- NURTEC ODT may be taken with or without food.
- Take NURTEC ODT immediately after opening the blister pack. Do **not** store the tablets outside the blister pack for future use.

Instructions for Use of NURTEC ODT:



1. Using dry hands, peel back the foil covering of one blister pack and gently remove the tablet. Do **not** push the tablet through the foil.



2. As soon as the blister pack is opened, remove the tablet and place it on or under the tongue, where it will dissolve. It can then be swallowed without any additional liquid.

Usual dose:

Your healthcare professional will tell you the right dose of NURTEC ODT for you. This will depend on if you take certain medicines such as fluconazole, erythromycin, diltiazem, quinidine, verapamil, and cyclosporine.

The recommended dose is one tablet of NURTEC ODT (75 mg) once a day, as needed.

Do **not** take more than the maximum dose of 75 mg per day.

Overdose

If you think you, or a person you are caring for, have taken too much NURTEC ODT, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using NURTEC ODT?

These are not all the possible side effects you may have when taking NURTEC ODT. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of NURTEC ODT may include:

- nausea.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Allergic reaction: shortness of breath, rash, difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick, vomiting, hives, or swelling of the face, lips, tongue or throat.			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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.htm>) 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 NURTEC ODT in the blister pack that it comes in at room temperature (15°C to 30°C).

Keep out of reach and sight of children.

If you want more information about NURTEC ODT:

- Talk to your healthcare professional;
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.pfizer.ca), or by calling 1-800-463-6001.

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