

PATIENT INFORMATION

NURTEC® ODT (NUR-tek)

(rimegepant)

orally disintegrating tablets (ODT), for sublingual or oral use

What is NURTEC ODT?

NURTEC ODT is a prescription medicine used in adults for the:

- acute treatment of migraine attacks with or without aura
- preventive treatment of episodic migraine

It is not known if NURTEC ODT is safe and effective in children.

Do not take NURTEC ODT if you are:

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

See the end of this leaflet for a complete list of ingredients in NURTEC ODT.

Before you take NURTEC ODT, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure.
- have circulation problems in your fingers and toes.
- have liver problems.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if NURTEC ODT will harm your unborn baby. There is a pregnancy exposure registry for women who take NURTEC ODT during pregnancy. The study is named MONITOR (Migraine Observational NURTEC Pregnancy Registry). A registry is a study. The purpose of this registry is to collect information about your health and the health of your baby. Your healthcare provider can help you enroll in this registry. You may also enroll yourself or get more information about the registry by calling 1-877-366-0324, emailing nurtecpregnancyregistry@ppd.com, or by visiting nurtecpregnancyregistry.com.
- are breastfeeding or plan to breastfeed. Very small amounts of NURTEC ODT pass into your breast milk. Talk with your healthcare provider about the best way to feed your baby if you take NURTEC ODT.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take NURTEC ODT?

- Take NURTEC ODT exactly how your healthcare provider tells you to.
- For the acute treatment of migraine attacks when they occur, NURTEC ODT can be taken 1 time each day as needed. You should not take more than 1 tablet in 24 hours.
 - It is not known if it is safe to take more than 18 doses of NURTEC ODT in 30 days.
- For the preventive treatment of episodic migraine, take NURTEC ODT 1 time every other day.
- To take NURTEC ODT:
 - Use dry hands when opening the blister pack.
 - Peel back the foil covering of one blister and gently remove NURTEC ODT. Do not push NURTEC ODT through the foil.
 - As soon as the blister is opened, remove NURTEC ODT and place on or under the tongue.
 - NURTEC ODT will dissolve and no drink or water is needed.
 - Take NURTEC ODT immediately after opening the blister pack. Do not store NURTEC ODT outside the blister pack for future use.
- If you take too much NURTEC ODT, go to the nearest emergency room right away.

What are the possible side effects of NURTEC ODT?

NURTEC ODT may cause serious side effects including:

- **Allergic reactions.** Allergic reactions, including trouble breathing and rash, can happen after you take NURTEC ODT. This can happen days after you take NURTEC ODT. Call your healthcare provider 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
 - Trouble breathing
- **High blood pressure.** High blood pressure or worsening of high blood pressure can happen after you take NURTEC ODT. Contact your healthcare provider if you have an increase in blood pressure.
- **Raynaud's phenomenon.** A type of circulation problem can worsen or happen after you take NURTEC ODT. Raynaud's phenomenon can lead to your fingers or toes feeling numb, cool, or painful, or changing color from pale, to blue, to red. Contact your healthcare provider if these symptoms occur.

The most common side effect of NURTEC ODT in acute treatment of migraine attacks with or without aura is:

- nausea

The most common side effects of NURTEC ODT in preventive treatment of episodic migraine are:

- nausea
- stomach pain
- indigestion

These are not the only possible side effects of NURTEC ODT.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NURTEC ODT?

- Store NURTEC ODT in the blister package that it comes in.
- Store NURTEC ODT at room temperature between 68°F to 77°F (20°C to 25°C).

Keep NURTEC ODT and all medicines out of the reach of children.

General information about the safe and effective use of NURTEC ODT:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NURTEC ODT for a condition for which it was not prescribed. Do not give NURTEC ODT to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about NURTEC ODT that is written for health professionals.

What are the ingredients in NURTEC ODT?

Active ingredient in NURTEC ODT: rimegepant

Inactive ingredients in NURTEC ODT: benzyl alcohol, eucalyptol, gelatin, limonene, mannitol, menthol, menthone, menthyl acetate, sucralose, and vanillin



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For more information, go to www.nurtec.com or call 1-833-4NURTEC.

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This Patient Information has been approved by the U.S. Food and Drug Administration

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