For the acute treatment of migraine with or without aura in adults

Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

WITH NURTEC ODT, PATIENTS CAN QUICKLY TAKE ACTION AGAINST A MIGRAINE ATTACK

Nurtec ODT can be taken at the first symptoms of a migraine attack for acute treatment[1]

*At 2 hours, 21.2% of patients on Nurtec ODT achieved migraine pain freedom vs 10.9% on placebo ($P<0.001$); and 35.1% achieved freedom from most bothersome symptom (MBS) vs 26.8% on placebo ($P=0.001$) (co-primary endpoint). From 2 to 48 hours, 42.2% of patients on Nurtec ODT had sustained pain relief vs 25.2% on placebo; ($P<0.0001$).[1-3]

SELECT IMPORTANT SAFETY INFORMATION

Contraindications: Hypersensitivity to Nurtec ODT or any of its components.

Warnings and Precautions

Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue Nurtec ODT and initiate appropriate therapy. Serious hypersensitivity reactions have included dyspnea and rash and can occur days after administration.

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RAPID RELIEF AND ***RETURN TO NORMAL FUNCTION***

With Nurtec ODT, patients achieved pain freedom at 2 hours and pain relief as soon as 1 hour.[1-3]
Help your patients experience fast relief and get them back to their lives.

2
HOURS
POST-DOSE

Freedom from pain and MBS

- **21.2%** of patients on Nurtec ODT achieved migraine pain freedom vs **10.9%** on placebo; Δ10.3* (*P*<0.001) **(co-primary endpoint)**[1]
- **35.1%** achieved freedom from most bothersome symptom (MBS) vs **26.8%** on placebo; Δ8.3* (*P*=0.001) **(co-primary endpoint)**[1]

Pain relief and return to normal function

- **59.3%** of patients on Nurtec ODT achieved pain relief vs **43.3%** on placebo; Δ16.1%* (*P*<0.001) **(select secondary endpoint)**[1]
- **38.1%** of patients returned to normal function vs **25.8%** on placebo; Δ12.3%* (*P*<0.001) **(select secondary endpoint)**[1]

1
HOUR
POST-DOSE

Pain relief and return to normal function

- **36.8%** of patients on Nurtec ODT achieved pain relief vs **31.2%** on placebo; Δ5.5%* (*P*=0.0314) **(select secondary endpoint)**[2,3]
- **22.3%** had returned to normal function vs **15.8%** on placebo; Δ6.4%* (*P*=0.0025) **(select secondary endpoint)**[2,3]

STUDY DESIGN

*Risk difference from placebo based on Cochran-Mantel-Haenszel method.[2]

SELECT IMPORTANT SAFETY INFORMATION
Warnings & Precautions (cont'd)
Hypertension: Development of hypertension and worsening of pre-existing hypertension have been reported following the use of CGRP antagonists, including Nurtec ODT, in the postmarketing setting.
Monitor patients for new-onset hypertension or worsening of pre-existing hypertension and consider whether discontinuation is warranted.
Raynaud's Phenomenon: Development of Raynaud's phenomenon and recurrence or worsening of pre-existing Raynaud's phenomenon have been reported in the postmarketing setting following the use of CGRP antagonists, including Nurtec ODT.
If signs or symptoms of Raynaud's phenomenon develop, discontinue Nurtec ODT. Patients should be evaluated by a healthcare provider if symptoms do not resolve. Patients with a history of Raynaud's phenomenon should be monitored for and informed about the possibility of worsening or recurrence of signs and symptoms.

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SINGLE DOSE, ***LASTING RELIEF***

With just 1 dose, many patients experienced sustained pain relief without the need for rescue medication.[1-3]

2 DAYS

of relief with 1 dose

- From 2 to 48 hours, 42.2% of patients on Nurtec ODT had sustained pain relief vs 25.2% on placebo; Δ16.9%* (*P*<0.0001) (select secondary endpoint)[2,3]

86%

of patients on Nurtec ODT did not take a rescue medication

- 86% of patients on Nurtec ODT did not take a rescue medication within 24 hours post-dose vs 71% on placebo; Δ15%* (*P*<0.0001) (select secondary endpoint)[1]

STUDY DESIGN

*Risk difference from placebo based on Cochran-Mantel-Haenszel method.[2]

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions: The most common adverse reactions for Nurtec ODT vs placebo were nausea (2.7% vs 0.8%) and abdominal pain/dyspepsia (2.4% vs 0.8%).

Drug Interactions: Avoid concomitant administration of Nurtec ODT with strong inhibitors of CYP3A4 or strong or moderate inducers of CYP3A. Avoid another dose of Nurtec ODT within 48 hours when it is administered with moderate inhibitors of CYP3A4 or potent inhibitors of P-gp.

Use in Specific Populations: *Pregnancy:* It is not known if Nurtec ODT can harm an unborn baby. *Lactation:* The transfer of rimegepant into breast milk is low (<1%). *Hepatic impairment:* Avoid use of Nurtec ODT in persons with severe hepatic impairment. *Renal impairment*: Avoid use in patients with end-stage renal disease.

INDICATIONS

Nurtec ODT is indicated in adults for the:

• acute treatment of migraine with or without aura

• preventive treatment of episodic migraine

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Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

TAKE ON THE GO

One dissolvable 75 mg tablet[1]

- No water needed, can be taken with or without food[1]
- Dissolves rapidly within seconds[4]
- The ODT formulation may be helpful for patients who experience nausea and vomiting[2]
- T_{max} of 1.5 hours and an elimination half-life of ~11 hours[1]
- Should be stored at controlled room temperature, 68°F to 77°F with excursions permitted between 59°F to 86°F[1]

WELL-STUDIED SAFETY PROFILE

Generally well tolerated in clinical trials

- The most common adverse event (AE) with acute treatment was nausea (Nurtec ODT 2%; placebo 0.4%)[1]
- In clinical trials, Nurtec ODT was not associated with serious adverse events, and <3% of patients discontinued due to AEs[5,*†]
- Not contraindicated in patients with stable cardiovascular disease or risk factors[1]
- The gepant mechanism of action has not been associated with medication overuse headache (MOH)[6]

STUDY DESIGN

*AEs considered by the investigator to be possibly (1 serious AE) or unlikely (9 serious AEs) related to study drug were reported in 10 (0.6%) participants.[7]

†A serious adverse event is any event that meets any of the following criteria at any dose: death, life-threatening, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability, congenital anomaly/birth defect in the offspring of a subject who received rimegepant 75 mg, and otherreceived rimegepant 75 mg, and other.

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Nurtec® ODT (rimegepant)
orally disintegrating tablets 75 mg

FOR YOUR PATIENTS WHO NEED A TREATMENT THAT CAN PROVIDE QUICK AND SUSTAINED RELIEF, ***CHOOSE NURTEC ODT***[1]

ONE DISSOLVABLE 75 MG TABLET NO WATER NEEDED[1]

1 HOUR

DEMONSTRATED RAPID RELIEF AND RETURN TO NORMAL FUNCTION[2]

2 DAYS

DELIVERED SUSTAINED RELIEF UP TO 48 HOURS[2]

86%

OF PATIENTS ON NURTEC ODT DID NOT TAKE A RESCUE MEDICATION WITHIN 24 HOURS[1]

WELL-STUDIED SAFETY PROFILE[1]

NURTEC ODT is the **only** migraine medication indicated for acute treatment of migraine and preventive treatment of episodic migraine in adults[1]

Preventive treatment is one 75 mg ODT taken every other day. The maximum dose in a 24-hour period is 75 mg.
The safety of using more than 18 doses in a 30-day period has not been established.[1]

NURTEC ODT HAS 97% COMMERCIAL COVERAGE*

*Managed Markets Insights & Technology LLC as of 10/30/24.

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#1
PRESCRIBED MIGRAINE TREATMENT IN ITS CLASS
SINCE 8/6/21*

*Per IQVIA as oral brand in class (oral CGRP receptor antagonists): number one prescribed and number one in new prescriptions, since 08/06/21. Data current as of 10/30/24.

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(rimegepant)
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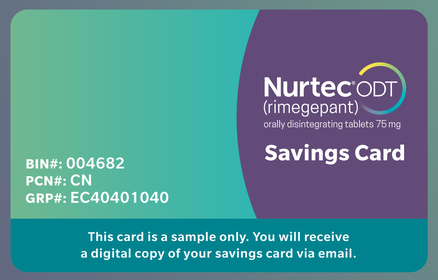

97% COMMERCIAL COVERAGE

Nurtec has 97% commercial coverage and eligible patients may pay as little as $0 per month with the savings card.†

†Eligible commercially insured patients can, for one time only, access Nurtec ODT at no cost while benefits are being verified for one prescription fill, with a maximum of 16 tablets total. Insurance coverage must be approved by the payor for patients to continue receiving Nurtec ODT with no out-of-pocket cost. No membership fees. Only available for commercially insured patients. This is not health insurance. Maximum annual benefit of $7,000. The full terms and conditions can be accessed at nurtec.com/savings#terms-and-conditions.

INDICATIONS

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

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Please click here for full Prescribing Information.

References: 1. Package insert. Pfizer Inc. **2.** Croop R, Goadsby PJ, Stock DA, et al. Efficacy, safety, and tolerability of rimegepant orally disintegrating tablet for the acute treatment of migraine: a randomized, phase 3, double-blind, placebo-controlled trial. *Lancet*. 2019;394(10200):737-745. **3.** Data on File. BHV3000-303. Pfizer Inc. **4.** Abay FB, Ugurlu T. Orally disintegrating tablets: a short review. *J Pharm Drug Devel*. 2015;3(3):303-311. doi: 10.15744/2348-9782.3.303 **5.** Croop R, Berman G, Kudrow D, et al. A multicenter, open-label long-term safety study of rimegepant for the acute treatment of migraine. *Cephalalgia*. 2024;44(4):1-11. **6.** van Hoogstraten WS, MaassenVanDenBrink A. The need for new acutely acting antimigraine drugs: moving safely outside acute medication overuse. *J Headache Pain*. 2019;20(1):54. **7.** Croop R, Bhardwaj R, Anderson MS, et al. Bioequivalence of rimegepant, a small molecule CGRP receptor antagonist, administered as an oral tablet, a sublingual orally disintegrating tablet, and a supralingual orally disintegrating tablet: two phase 1 randomized studies in healthy adults. *Cephalalgia*. 2024;44(2):1-12. **8.** Data on File. RIM 130. Pfizer Inc.

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Acute Study Design

Nurtec ODT (rimegepant) 75 mg was evaluated in a multicenter, double-blind, placebo-controlled, randomized study with 1466 total patients to treat a migraine of moderate-to-severe pain intensity. A tablet form was also assessed in 2 similarly designed studies, and bioequivalence has been established.[2,7]

SCREENING PHASE[2]

Men and women aged 18 years and older with at least a 1-year history of 2 to 8 moderate or severe migraine attacks per month with or without aura*

Approximately 85% of patients were female, 74% were White, 21% were Black, and 17% were Hispanic or Latino. The mean age at study entry was 40 years (range 18-75 years of age).[1]

Randomization 1:1[2]

Patients were given one dose to take during an attack of moderate or severe pain intensity.†

TREATMENT PHASE[2]
up to 45 days

- **Nurtec ODT 75 mg** (n=732)
- **Placebo** (n=734)

Rescue medication (eg, NSAIDs, acetaminophen, and/or an antiemetic) was allowed 2 hours after the initial treatment. Other forms of rescue medication such as triptans were not allowed within 48 hours of initial treatment.[1]

END OF TREATMENT VISIT[2]
within 7 days after dosing of study medication

- **Nurtec ODT 75 mg** (n=679)
- **Placebo** (n=689)

Within 7 days of the treated attack (plus 2 days [ie, up to 9 days], if necessary), participants returned to the study site for review of the eDiary, assessment of medication compliance, and monitoring of tolerability and safety.[2]

Co-primary endpoints at 2 hours post-dose[2]:

- Freedom from pain: defined as a reduction in headache severity from moderate/severe at baseline to no pain
- Freedom from most bothersome symptom (MBS): defined as absence of the most bothersome migraine-associated symptom (photophobia, phonophobia, or nausea)

Select secondary endpoints at various time points[2]:

- Pain relief and sustained pain relief‡
- Ability and sustained ability to function normally
- Freedom and sustained freedom from MBS and freedom§ and sustained freedom from pain
- No rescue medication within 24 hours‖

Inclusion Criteria[2]

Eligible participants included men and women aged 18 years and older with at least a 1-year history of migraine with or without aura according to the criteria of the 3rd edition of the *International Classification of Headache Disorders* (beta version); migraine onset before age 50; at least 2 and not more than 8 migraine attacks of moderate or severe intensity per month, and fewer than 15 days per month with migraine or nonmigraine headache within the past 3 months. Participants had to be able to distinguish migraine attacks from attacks of tension-type and cluster headache, and those taking preventive migraine medication had to be on a stable dose for at least 3 months before study entry. If all other criteria for inclusion were met, participants with contraindications to triptans could be included.

Exclusion Criteria[2]

Participants were excluded if they had any medical condition that might interfere with study assessments of efficacy and safety or expose participants to undue risk of a significant adverse event, as decided by the investigator (case by case). Participants were also excluded if they had been treated for or showed evidence of alcohol or drug abuse within the past 12 months; had a history of drug or other allergy that made them unsuitable for participation; or had electrocardiogram (ECG) or laboratory test findings that raised safety or tolerability concerns.

*Patients with stable cardiovascular (CV) disease and CV risk factors were permitted. Stable CV disease was defined as no events within the last 6 months. Subjects enrolled were stable with ischemic coronary artery disease (3 rimegepant, 1 placebo), history of stroke or transient ischemic attack (3 rimegepant, 2 placebo), peripheral vascular disease (2 rimegepant, 1 placebo), Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders (1 rimegepant, 1 placebo), uncontrolled hypertension (1 placebo subject).[8]
†Patients were required to wait until their migraine was of moderate-to-severe intensity before treating with the study medication.[2]
‡Pain relief: defined as the reduction in headache pain from moderate/severe (2 or 3) at baseline to mild/no pain (1 or 0).[2]
§Return to normal function: defined as the reduction from mild impairment, severe impairment, or required bedrest (1, 2, or 3) at baseline to normal functioning (0).[2]
‖Rescue medication: NSAIDs, acetaminophen, and/or antiemetic.[1]