Pfizer | Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

In the First Head-to-Head Study Comparing Two CGRP Antagonists,

EMGALITY® (galcanezumab) Failed to Demonstrate Superiority Over Nurtec ODT® (rimegepant) in Prevention of Episodic Migraine[1]

Sponsored by Eli Lilly, the CHALLENGE-MIG trial did not meet its primary endpoint of a ≥50% reduction in monthly migraine headache days from baseline across the 3-month double-blind treatment phase[1]

Nurtec ODT Prevention Pivotal Data

CHALLENGE-MIG Study Design

Emgality is a calcitonin gene-related peptide (CGRP) antagonist indicated in adults for the preventive treatment of migraine and the treatment of episodic cluster headache.[2]
Nurtec ODT is a CGRP receptor antagonist indicated for the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults.[3]
Information related to the CHALLENGE-MIG trial is not included in the Prescribing Information for Nurtec ODT.

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.
Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

CHALLENGE-MIG

Emgality Did Not Meet the Study's Primary Objective of Superiority Over Nurtec ODT[1]

CHALLENGE-MIG Primary Endpoint and Results[1]

The proportion of participants with at least a 50% reduction in monthly migraine headache days* (≥50% response rate) from baseline across the 3-month double-blind treatment period:

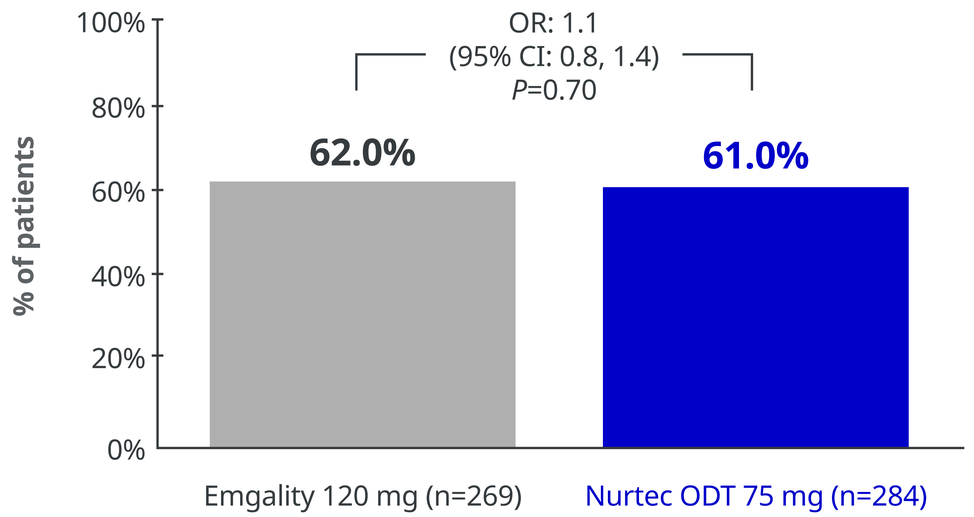
- 62.0% in the Emgality group
- 61.0% in the Nurtec ODT group

At baseline, participants in this study had an average of 8.4 migraine headache days per month, with 54% of participants having ≥8 migraine headache days per month at baseline.

There was no statistically significant difference between treatment groups; odds ratio 1.1 (95% CI: 0.8, 1.4; *P*=0.70).

In accordance with the multiple testing procedure, prespecified secondary endpoints cannot be considered statistically significant because the primary endpoint was not met.

PRIMARY ENDPOINT: PROPORTION OF PARTICIPANTS WITH ≥50% REDUCTION IN MONTHLY MIGRAINE HEADACHE DAYS [1,†]



CI=confidence interval; OR=odds ratio.
†Proportion of participants with ≥50% reduction in monthly migraine headache days from baseline across the 3-month double-blind period.

~100% TREATMENT COMPLIANCE WITH EVERY-OTHER-DAY DOSING WAS SEEN IN THE STUDY[1]

Across the 3-month double-blind period, the Nurtec ODT group had 100.8% treatment compliance with every-other-day dosing, and the Emgality group had 99.8% treatment compliance.

Nurtec ODT Prevention Pivotal Data

CHALLENGE-MIG Study Design

*A migraine headache day was defined as a calendar day on which a migraine headache or probable migraine headache occurred.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and 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.

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

CHALLENGE-MIG

Adverse Events

- No clinically meaningful differences in vital signs or laboratory parameters were seen between study intervention groups[1]

- Six participants (1.0%) discontinued the study due to an adverse event[1]:
  - 2 (0.7%) in the Emgality group (depressed level of consciousness, injection-site pain)
  - 4 (1.4%) in the Nurtec ODT group (fatigue, migraine, pulmonary embolism, and somnolence)

- One serious adverse event was reported: a pulmonary embolism occurred in a participant receiving Nurtec ODT with an undisclosed baseline history of pulmonary embolism[1]
  - The participant recovered from the event and discontinued the study
  - The event was considered by the investigator to be related to the blinded study intervention

Treatment-emergent adverse events and serious adverse events[1]

Variable, n (%)	Emgality* 120 mg (n=287)	Nurtec ODT† 75 mg (n=293)
Participants with ≥1 TEAE	60 (20.9)	60 (20.5)
TEAEs occurring in ≥3 participants (overall)		
COVID-19	12 (4.2)	5 (1.7)
Nausea	3 (1.0)	4 (1.4)
Fatigue	2 (0.7)	4 (1.4)
Injection-site pain	2 (0.7)	4 (1.4)
Nasopharyngitis	1 (0.3)	5 (1.7)
Influenza	3 (1.0)	2 (0.7)
Anemia	3 (1.0)	1 (0.3)
Migraine	0	4 (1.4)
Sinusitis	1 (0.3)	3 (1.0)
Constipation	3 (1.0)	0
Diarrhea	2 (0.7)	1 (0.3)
Hypertension	1 (0.3)	2 (0.7)
Upper respiratory tract infection	1 (0.3)	2 (0.7)
Vertigo	2 (0.7)	1 (0.3)
Discontinuation from study due to an AE	2 (0.7)	4 (1.4)
Serious adverse events	0	1 (0.3)

AE=adverse event; TEAE=treatment-emergent adverse event.
*Participants received Emgality 120 mg and placebo orally disintegrating tablet.
†Participants received Nurtec ODT 75 mg and subcutaneous placebo injection.

Nurtec ODT Prevention Pivotal Data | CHALLENGE-MIG Study Design

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.

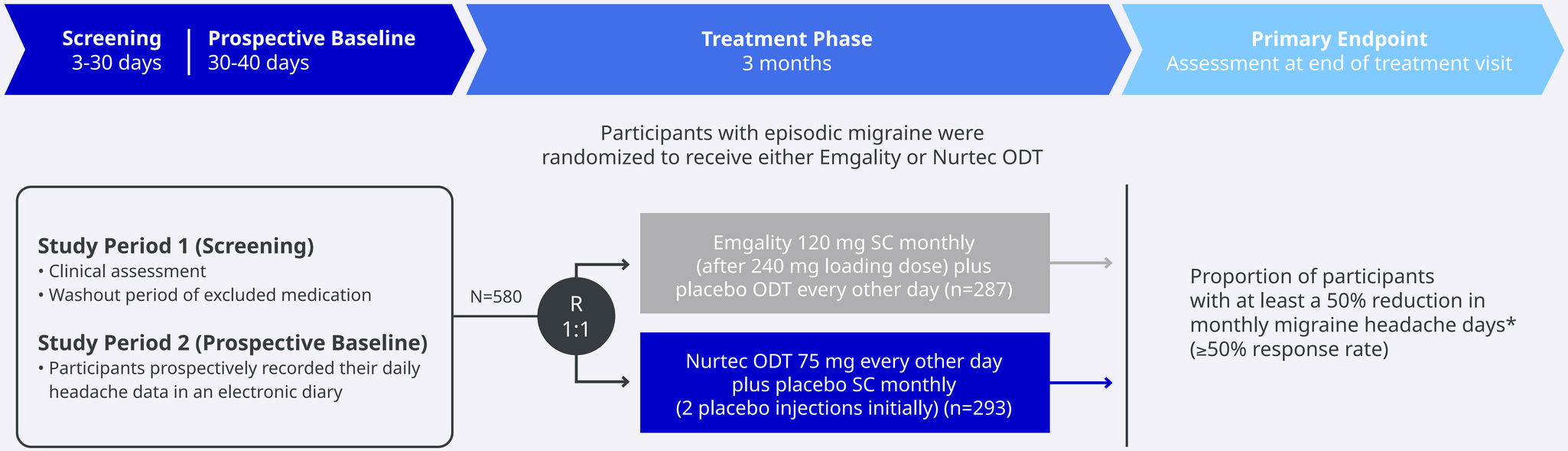
INDICATIONS

Nurtec ODT is indicated in adults for the:
- acute treatment of migraine with or without aura
- preventive treatment of episodic migraine

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

CHALLENGE-MIG

CHALLENGE-MIG Study Design[1]



Protocol-specified acute migraine headache medications (acetaminophen; non-steroidal anti-inflammatory drugs; triptans; ergotamine and derivatives; aspirin, caffeine, and acetaminophen combination; or combinations thereof), as needed, were permitted during all study periods. Gepants, including rimegepant, were not allowed to be used for acute migraine treatment.[1]

ODT=orally disintegrating tablet; SC=subcutaneous.
*A migraine headache day was defined as a calendar day on which a migraine headache or probable migraine headache occurred.

Demographics and Inclusion/Exclusion Criteria

Nurtec ODT Prevention Pivotal Data

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.

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

CHALLENGE-MIG STUDY DESIGN: SELECT INCLUSION AND EXCLUSION CRITERIA AND DEMOGRAPHICS

Select Inclusion Criteria[1]

- Adults aged 18-75 years with ≥1-year history of migraine with or without aura as per ICHD-3
- Migraine onset prior to age 50
- During the baseline period: 4-14 migraine headache days per month and at least 2 migraine attacks per month
- During the baseline period: 80% compliance rate in using electronic diary
- Women of childbearing potential agreed to use birth control during the study and for 5 months after the last dose

Select Exclusion Criteria[1,4]

- Patients with a history of ≥15 headache days per month or a diagnosis of chronic migraine per ICHD-3
- Preventive migraine therapy use within 5 days of baseline visit and during the study
- Prior exposure or current use of a CGRP antagonist (monoclonal antibody or gepant) and those with known hypersensitivity to rimegepant or galcanezumab
- Concomitant use of strong or moderate CYP3A4 inhibitors, strong or moderate CYP3A inducers, or inhibitors of P-gp and BRCP
- Acute cardiovascular events and/or a serious cardiovascular risk based on ECG at screening, or a history of myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass graft, or stroke within 6 months before screening
- Hepatic disease (based upon liver tests)
- Pregnant or nursing women

SELECT BASELINE PARTICIPANT CHARACTERISTICS[1]

Characteristic	Emgality® (galcanezumab) (n=287)	Nurtec ODT® (rimegepant) (n=293)	Total (N=580)
Age, mean (SD) year	41.7 (12.6)	42.3 (11.3)	42.0 (12.0)
Female, n (%)	244 (85.0)	238 (81.2)	482 (83.1)
Race, n (%)			
White	236 (83.1)	232 (79.2)	468 (81.1)
Black	34 (12.0)	44 (15.0)	78 (13.5)
Asian	8 (2.8)	11 (3.8)	19 (3.3)
Other*	6 (2.1)	6 (2.0)	12 (2.1)
Migraine headache days per month, mean (SD)	8.5 (2.9)	8.3 (2.9)	8.4 (2.9)
Frequency of migraine headache days per month, n (%)			
<8 days/month	128 (44.6)	136 (46.4)	264 (45.5)
≥8 days/month	159 (55.4)	157 (53.6)	316 (54.5)
Acute medication use days per month,† mean (SD)	6.8 (4.0)	6.9 (3.7)	6.9 (3.8)
Prior migraine preventive treatments, n (%)			
No prior preventive treatment	248 (86.4)	240 (81.9)	488 (84.1)
Prior treatment and failed ≥1 medication	25 (8.7)	39 (13.3)	64 (11.0)

BRCP=breast cancer-resistant protein; CGRP=calcitonin gene-related peptide; CYP=cytochrome P450; ECG=electrocardiogram; ICHD-3=International Classification of Headache Disorders, 3rd Edition; P-gp=P-glycoprotein; SD=standard deviation.
*American Indian or Alaska native, native Hawaiian or other Pacific Islander, or multiple.
†Regardless of any headache occurrence.

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.

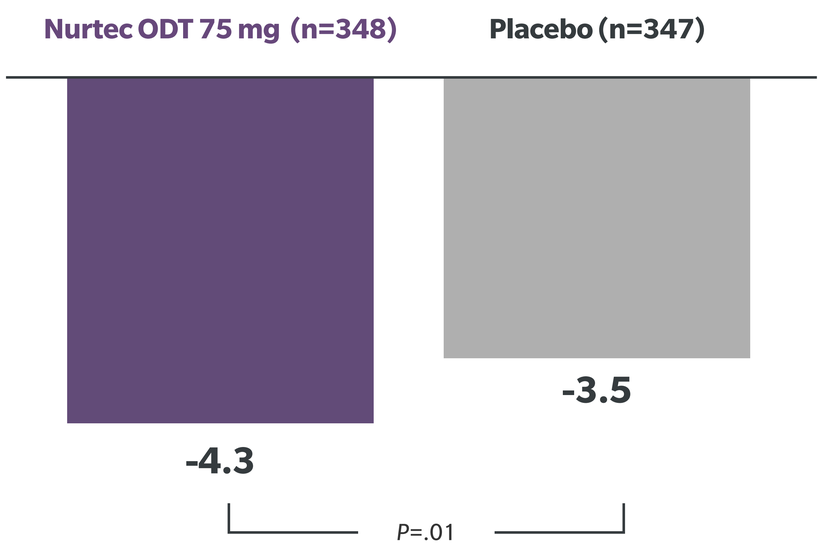
Raynaud's Phenomenon: Development of Raynaud's phenomenon and recurrence or worsening of pre-existing Raynaud's phenomenon have been reported in the postmarketing setting following the use of CGRP antagonists, including Nurtec ODT.

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.

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

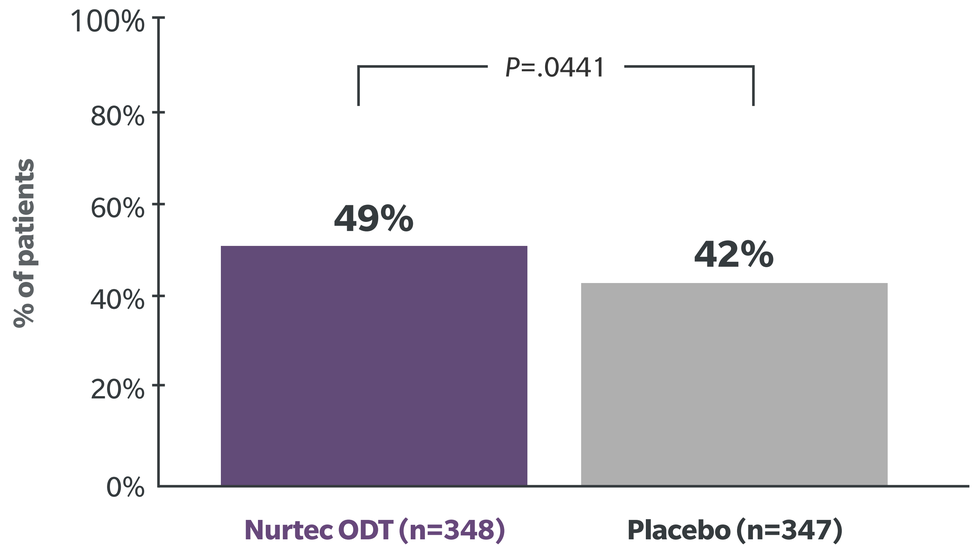
Nurtec ODT Effectively Prevented Attacks in Patients With Episodic Migraine[3]

PRIMARY ENDPOINT: REDUCTION IN MEAN MONTHLY MIGRAINE DAYS (MMDs) DURING WEEKS 9-12[3,*]



*Analyzed using a generalized linear mixed-effects model with treatment group, preventive migraine medication use at randomization, study month, and month-by-treatment group interaction as fixed effects and participant as random effect.[5]

SELECT SECONDARY ENDPOINT: PROPORTION OF PARTICIPANTS WITH ≥50% REDUCTION IN MODERATE-TO-SEVERE MMDs DURING WEEKS 9-12[3,5]



Baseline MMDs during the 4-week observation period were 10.3 for rimegepant-treated participants and 9.9 for placebo-treated participants.[5]

Prevention Trial Study Design

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

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

Pfizer | Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

NURTEC ODT PIVOTAL TRIAL

Nurtec ODT Offers Generally Well-Tolerated Migraine Prevention in an Orally Disintegrating Tablet[3,5]

WELL-STUDIED SAFETY PROFILE

Nurtec ODT was not associated with any serious treatment-related adverse events in a clinical trial of preventive treatment[3,5,*]

In the long-term open-label extension study, constipation rates were low and within the expected range of the general population[6,7]
Constipation incidence ranged from 1.5% (23/1514) with as-needed use over 52 weeks to 1.7% (5/286) with every-other-day plus as-needed use over 12 weeks.[6]

Nurtec ODT does not have cardiovascular contraindications or precautions[3]

Prevention Trial Study Design

*A serious adverse event is any event that meets any of the following criteria at any dose: death, life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, congenital anomaly/birth defect in the offspring of a subject who received rimegepant, and others.[9]

Summary of adverse events (AEs) in the pivotal trial safety population [3,5,8]

Event, No. (%)	Rimegepant (n=370)	Placebo (n=371)
Patients with any AE	133 (36)	133 (36)
AEs, ≥2% of patients treated with rimegepant		
Abdominal pain/dyspepsia	9 (2)	3 (1)
Nasopharyngitis	13 (4)	9 (2)
Nausea	**10 (3)**	**3 (1)**
Urinary tract infection	9 (2)	8 (2)
Upper respiratory tract infection	8 (2)	10 (3)
Patients with mild AE	92 (25)	91 (25)
Patients with moderate AE	64 (17)	62 (17)
Patients with AEs related to treatment	40 (11)	32 (9)
Serious AEs	3 (1)	4 (1)
Serious AEs related to treatment	0	1 (<1)
AEs leading to discontinuation	7 (2)	4 (1)

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.

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

NURTEC ODT PIVOTAL TRIAL

Preventive Study Design

Rimegepant 75 mg was evaluated for the preventive treatment of migraine in a multi-center, double-blind, randomized, placebo-controlled clinical trial of 747 total patients.[3]

BASELINE OBSERVATION PHASE[3,5]
4 weeks

Patients had a history of 4 to 18 moderate or severe monthly migraine attacks.

Patients with ≥6 migraine days and ≤18 headache days during the observation phase were eligible for the treatment phase.

Randomization 1:1

TREATMENT PHASE[3]
12 weeks

Rimegepant 75 mg (n=373)

Every-other-day dosing

Placebo (n=374)

Patients were allowed to use acute headache treatments (eg, triptans, NSAIDs, acetaminophen, antiemetics) as needed.

EXTENSION PHASE[5,10]
12 months

Patients were allowed to continue in an open-label extension study for an additional 12 months.

Patients took rimegepant 75 mg every-other-day and were allowed to use rimegepant 75 mg on non-scheduled days as needed. Triptans were prohibited during the open-label, extension phase.

PRIMARY ENDPOINT:
- Change from baseline in the mean number of monthly migraine days (MMDs) during weeks 9 through 12[3]

SELECT SECONDARY ENDPOINT:
- Percentage of patients who achieved a ≥50% reduction in moderate-to-severe MMDs during weeks 9 through 12[3]

Demographics and Inclusion/Exclusion Criteria

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.

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

PREVENTIVE STUDY DESIGN: SELECT INCLUSION AND EXCLUSION CRITERIA AND DEMOGRAPHICS

Select Inclusion Criteria[5,10]

- ≥1-year history of migraine (with or without aura) or chronic migraine consistent with a migraine diagnosis according to ICHD-3
- Age of onset before 50 years
- Migraine attacks lasting 4-72 hours on average if untreated
- 4-18 migraine attacks of moderate to severe intensity per month within the past 3 months before screening
- ≥6 migraine days during the observation period
- Ability to distinguish migraine attacks from tension/cluster headaches
- 1 prophylactic migraine medication permitted with stable dose for ≥3 months prior to the observation period (no CGRP receptor antagonists or anti-CGRP monoclonal antibodies)

Select Exclusion Criteria[5,10]

- >18 headache days during the observation period
- History of HIV, gastric or small intestine surgery, or a disease that causes malabsorption
- Subject history with current evidence of uncontrolled, unstable, or recently diagnosed cerebrovascular disease (eg, ischemic heart disease, coronary artery vasospasms, cerebral ischemia, myocardial infarction, acute coronary syndrome, PCI, cardiac surgery, stroke, transient ischemic attack)
- Uncontrolled hypertension or diabetes
- Major depressive episode within past 12 months; major depressive or anxiety disorder requiring medication; schizophrenia, bipolar disorder, or borderline personality disorder
- Other pain syndromes, psychiatric conditions, dementia, or significant neurological disorders
- Subjects are excluded if they have had no therapeutic response with >2 of the 8 medication categories for prophylactic treatment of migraine after an adequate therapeutic trial
- Body mass index ≥33 kg/m^2
- History of gallstones or cholecystectomy
- History of current unstable medical conditions

Nurtec is not indicated for the preventive treatment of chronic migraine in adults.[3]

CGRP=calcitonin gene-related peptide; HIV=human immunodeficiency virus; ICHD-3=International Classification of Headache Disorders, 3rd edition; PCI=percutaneous coronary intervention.

SELECT BASELINE PARTICIPANT CHARACTERISTICS[5]

Characteristic	Rimegepant 75 mg (n=370)	Placebo (n=371)
Age, mean (SD) year	41.3 (13.0)	41.1 (13.1)
Female, n (%)	300 (81.0)	313 (84.0)
Male, n (%)	70 (19.0)	58 (16.0)
Race		
White	295 (80%)	309 (83%)
Black or African American	62 (17%)	49 (13%)
Asian	1 (<1%)	7 (2%)
Multiple	6 (2%)	2 (1%)
Other*	6 (2%)	4 (1%)
History of chronic migraine		
Yes	78 (21%)	95 (26%)
No	292 (79%)	276 (74%)
Primary migraine type		
Without aura	220 (59%)	226 (61%)
With aura	150 (41%)	145 (39%)
Migraine days per month, mean	10.3	9.9
Migraine attacks per month, mean (moderate to severe)	7.8	7.8
Mean duration of untreated attacks, hours	24	24

*American Indian or Alaska Native, Native Hawaiian or other Pacific Islander.

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

Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

#1 PRESCRIBED MIGRAINE TREATMENT IN ITS CLASS SINCE 8/6/2021*

Think Nurtec ODT for Prevention of Episodic Migraine

FLEXIBLE
The ONLY medication indicated to both prevent migraine attacks and treat them when they strike[3,5]

EFFECTIVE
Proven preventive treatment shown in the pivotal trial[3,5]

GENERALLY WELL TOLERATED IN CLINICAL TRIALS
Well-studied safety profile[3,5]

ORALLY DISINTEGRATING TABLET
One simple 75-mg dosage strength[3]

For **PREVENTIVE** treatment of episodic migraine:
One 75-mg Nurtec ODT tablet every other day[3]

For **ACUTE** treatment of migraine attacks:
One 75-mg Nurtec ODT as needed[3]

The half-life of Nurtec ODT is ~11 hours.[3,†]

The maximum dose in a 24-hour period is 75 mg. The safety of using more than 18 doses for acute treatment in a 30-day period has not been established.[3]

*Per IQVIA as oral brand in class (oral CGRP receptor antagonists): #1 prescribed and #1 in new prescriptions, since 8/6/21. Data current as of 10/30/24.

†The elimination half-life was analyzed in healthy subjects.[3]

INDICATIONS

Nurtec ODT is indicated in adults for the:

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

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.

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.

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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.

Please click here for full Prescribing Information.

References: 1. Schwedt TJ, Myers Oakes TM, Martinez JM, et al. Comparing the efficacy and safety of galcanezumab versus rimegepant for prevention of episodic migraine: results from a randomized, controlled clinical trial. *Neurol Ther.* 2024;13(1):85-105. **2.** Emgality. Prescribing Information. Lilly USA, LLC. **3.** Nurtec ODT. Prescribing Information. Pfizer Inc. **4.** Supplement to: Schwedt TJ, Myers Oakes TM, Martinez JM, et al. Comparing the efficacy and safety of galcanezumab versus rimegepant for prevention of episodic migraine: results from a randomized, controlled clinical trial. *Neurol Ther.* 2024;13(1):85-105. **5.** Croop R, Lipton RB, Kudrow D, et al. Oral rimegepant for preventive treatment of migraine: a phase 2/3, randomised, double-blind, placebo-controlled trial. *Lancet.* 2020;397(10268): 51-60. **6.** Data on File. RIM MA-05. Pfizer Inc. **7.** Andromanakos N, Skandalakis P, Troupis T, et al. Constipation of anorectal outlet obstruction: pathophysiology, evaluation and management. *J Gastroenterol Hepatol.* 2006;21(4):638-646. **8.** Data on File. RIM MA-01 Pfizer Inc. **9.** Study BHV3000-303 Clinical Protocol. Clinicaltrials.gov. Published July 23, 2018. Accessed January 24, 2024. https://clinicaltrials.gov/ProvidedDocs/57/NCT03461757/Prot_000.pdf **10.** Supplement to: Croop R, Lipton RB, Kudrow D, et al. Oral rimegepant for preventive treatment of migraine: a phase 2/3, randomised, double-blind, placebo-controlled trial. *Lancet.* 2020; published online Dec 15.

Pfizer | Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg