Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

ACUTE | PREVENTIVE | IMPORTANT SAFETY INFORMATION

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

LONG-TERM TREATMENT DATA WITH NURTEC ODT

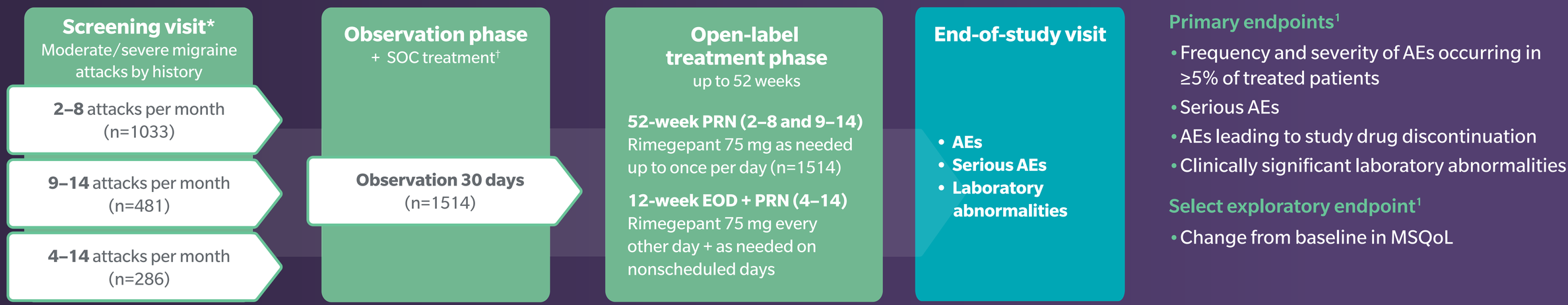
- Data from a 52-week multicenter, phase 2/3, open-label safety study for the acute treatment of migraine[1]
- Safety data from a 52-week open-label extension of a 12-week phase 2/3 study of Nurtec ODT for the preventive treatment of migraine[2]

ACUTE PIVOTAL STUDY | PREVENTIVE PIVOTAL STUDY

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.

LONG-TERM SAFETY STUDIED UP TO 52 WEEKS

Phase 2/3, Open-Label Study Design[1]



Primary endpoints[1]

- Frequency and severity of AEs occurring in ≥5% of treated patients
- Serious AEs
- AEs leading to study drug discontinuation
- Clinically significant laboratory abnormalities

Select exploratory endpoint[1]

- Change from baseline in MSQoL

Croop, *Cephalalgia* (2024)

- The 4–14 attacks per month treatment arm (n=286) did not utilize the FDA-approved dosing regimen for the acute treatment of migraine with or without aura in adults. This treatment arm was included in the analysis presented in the safety section but was excluded from the presentation of exploratory endpoints[1,3]
- This study evaluated a rimegepant 75 mg oral tablet formulation that was found to be bioequivalent to Nurtec ODT in a phase 1 study[4]

AE=adverse event; EOD=every other day; FDA=Food and Drug Administration; MSQoL=Migraine-Specific Quality of Life Questionnaire; PRN=as needed; SOC=standard of care.

*Overall, 51% of the patients enrolled in Study 201 had participated in a previous rimegepant study.[1]

†With the exception of triptans and acetaminophen, participants were allowed to take SOC migraine treatment, if needed, during the course of study.[1]

INCLUSION/EXCLUSION CRITERIA | REFERENCES

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.

Select Inclusion/Exclusion Criteria From the Long-Term Safety Study[1*]

Inclusion criteria

- Aged ≥18 years with history of migraine with or without aura
- A 1-year history of migraine attacks lasting 4–72 hours if untreated, with age of onset <50 years
- 2–14 migraine attacks per month of moderate to severe pain intensity within the 3 months prior to the screening period
- If using preventive medication, stable dose for ≥2 months
- Ability to distinguish migraine attacks from tension/cluster headaches
- Patients with contraindications for use of triptans were allowed as long as all other study entry criteria were met

Exclusion criteria

- History of basilar or hemiplegic migraine
- History of HIV disease
- History of uncontrolled, unstable, or recently diagnosed cardiovascular disease
- Uncontrolled hypertension or diabetes
- Body mass index ≥30 kg/m^2

HIV=human immunodeficiency virus.

*The full inclusion/exclusion criteria for Study 201 are available in Croop, *Cephalalgia* (2024).

Phase 3 Acute Pivotal 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.[4,5]

SCREENING PHASE[5]
3–28 days

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

85% of patients were female, 75% were White, 20% were African American, and 19% were Hispanic or Latino.[5]

Randomization 1:1

Patients were given one dose to take during a moderate to severe attack.[5]*

TREATMENT PHASE[3,5]
up to 45 days

Rimegepant 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.[3,5]

END-OF-TREATMENT VISIT[5]
within 7 days after dosing of study medication

Rimegepant 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.[5]

Coprimary endpoints at 2 hours postdose[3,5]

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

Select secondary endpoint[5]

- Sustained pain relief from 2–48 hours postdose

Key inclusion criteria[5]

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.

Key exclusion criteria[5]

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 ECG or laboratory test findings that raised safety or tolerability concerns.

Rapid and sustained relief[5,6]

- At 2 hours postdose, 21.2% of patients on Nurtec ODT achieved migraine pain freedom vs 10.9% on placebo, Δ10.3%† (*P*<0.0001), and 35.1% achieved freedom from MBS at 2 hours postdose vs 26.8% on placebo, Δ8.3%† (*P*=0.001) (coprimary endpoint); from 2–48 hours postdose, 42.2% of patients on Nurtec ODT had sustained pain relief vs 25.2% on placebo, Δ16.9%† (*P*<0.0001)

Low incidence of adverse events[3]

- The most common adverse event with acute treatment was nausea (Nurtec ODT 2%; placebo 0.4%)

ECG=electrocardiogram; MBS=most bothersome symptom; NSAID=nonsteroidal anti-inflammatory drug.

*Patients were required to wait until their migraine was of moderate to severe intensity before treating with the study medication.[5]

†Risk difference from placebo based on Cochran-Mantel-Haenszel method.[5]

MORE THAN 100,000 DOSES OF RIMEGEPANT 75 mg WERE ADMINISTERED ACROSS 1500+ PATIENTS[7]

Baseline Attack Frequency and Rimegepant 75 mg Exposure Over 52 Weeks[1,7]

	2–8 attacks per month (n=1033)	9–14 attacks per month (n=481)
Baseline moderate/severe migraine attacks per month, mean ± SD	4.9 ± 1.8	10.8 ± 1.6
Tablets per month, median (min, max)	4.9 (0.2, 27.6)	7.8 (0.7, 26.6)
Total rimegepant 75 mg doses	61,837	38,841

NSAID=nonsteroidal anti-inflammatory drug; SD=standard deviation.

Dosing parameters[1]

- Patients were allowed to treat migraine attacks of any severity (mild, moderate, or severe headache pain intensity) as needed with up to one rimegepant 75 mg oral tablet per calendar day for 52 weeks
- Rescue medication (eg, NSAIDs, acetaminophen, and/or an antiemetic) was allowed during the course of study. Use of triptans was prohibited during the long-term treatment phase

REFERENCES

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.

AEs WITH NURTEC ODT TREATMENT UP TO 52 WEEKS[1]

2.7%

OVERALL DISCONTINUATION RATE DUE TO AEs*

Event, n (%)	Up to 52 Weeks: PRN 2–8 (n=1033)	Up to 52 Weeks: PRN 9–14 (n=481)
AEs leading to discontinuation	24 (2.3)	16 (3.3)
AEs REPORTED ≥2% OVERALL		
Upper respiratory tract infection	108 (10.5)	38 (7.9)
Nasopharyngitis	72 (7.0)	41 (8.5)
Sinusitis	57 (5.5)	28 (5.8)
Urinary tract infection	40 (3.9)	21 (4.4)
Influenza	49 (4.7)	9 (1.9)
Back pain	36 (3.5)	14 (2.9)
Bronchitis	35 (3.4)	14 (2.9)
Nausea	33 (3.2)	15 (3.1)
Dizziness	26 (2.5)	13 (2.7)
Arthralgia	25 (2.4)	9 (1.9)

Most AEs reported were mild or moderate in intensity and judged by the investigator to be unrelated to treatment with rimegepant 75 mg

AE=adverse event; EOD=every other day; PRN=as needed.

*This percentage includes both the PRN and EOD + PRN treatment groups; the overall discontinuation rate due to AEs for the 2 PRN treatment cohorts was 2.6%.

REFERENCES

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.

RATES OF SERIOUS AEs WITH NURTEC ODT

2.6%

OF PATIENTS REPORTED SERIOUS AEs[1]*†

Serious AEs reported in >1 patient[1†‡]

- Accidental overdose, appendicitis, osteoarthritis, and pulmonary embolism (3 patients [0.2%] each)
- Constipation, pneumonia, and sepsis (2 patients [0.1%] each)

Serious AEs related to Nurtec ODT[†‡]

- 10 (0.6%) serious AEs were considered by the investigator to be possibly (1 serious AE) or unlikely (9 serious AEs) related to rimegepant 75 mg[1,8]
- No deaths were reported in this study[9]

AE=adverse event; EOD=every other day; PRN=as needed.

*This includes both the PRN and EOD + PRN treatment groups; the overall rate of serious AEs in the PRN treatment cohorts was 2.9%.[1]

†A serious adverse event was defined as 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/incapacity, congenital anomaly/birth defect in the offspring of a subject who received rimegepant, and others.[5]

‡Includes both the PRN and EOD + PRN treatment groups.[1]

REFERENCES

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.

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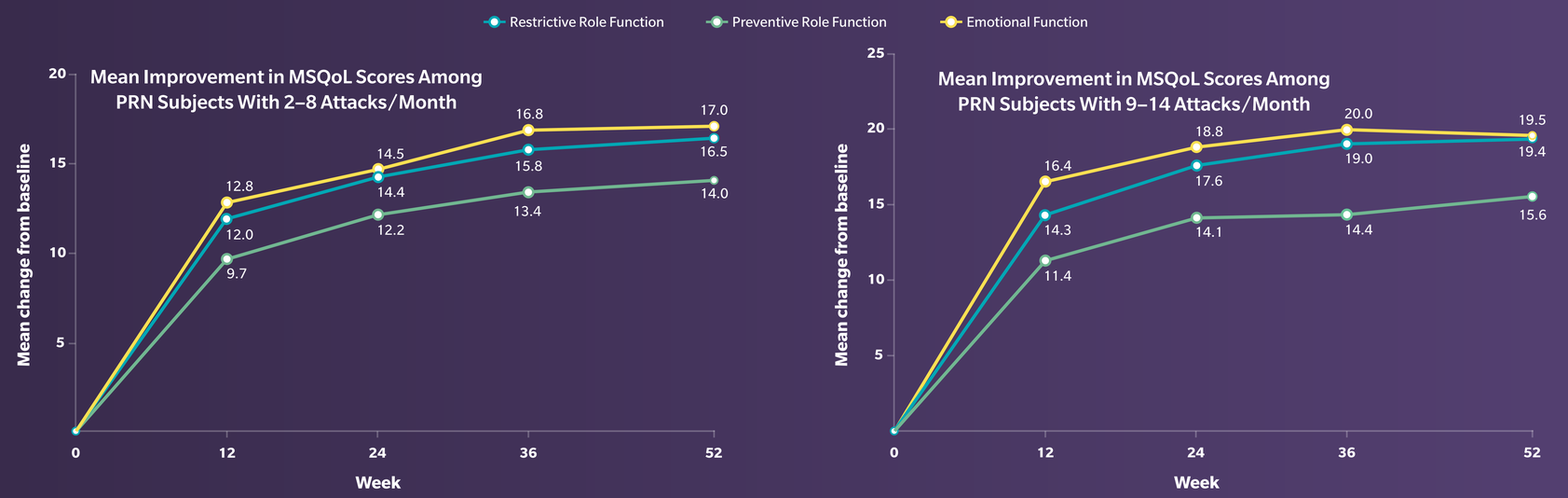
Please see additional Important Safety Information on the next page and click here for full Prescribing Information.

MIGRAINE-SPECIFIC QUALITY OF LIFE (MSQoL) SCORES UP TO 52 WEEKS[10]



MSQoL scores at baseline

The mean (SD) MSQoL scores at baseline were 52.7 (18.34) for Restrictive Role Function, 67.9 (20.50) for Preventive Role Function, and 60.9 (26.00) for Emotional Function, and were consistent across the 3 enrollment groups.[8]

Limitation

These data are from an exploratory endpoint of the open-label long-term safety study, which was not powered to determine a treatment effect on quality of life and may represent chance findings. Open-label extension studies tend to select patients who respond favorably to treatment, should be interpreted with caution, and may have limited generalizability. Comparisons should not be made across time points or patient cohorts. No conclusions can be drawn from this analysis.

MSQoL=Migraine-Specific Quality of Life Questionnaire; PRN=as needed; SD=standard deviation.

ABOUT MSQoL | REFERENCES

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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MIGRAINE-SPECIFIC QUALITY OF LIFE (MSQoL) SCORES UP TO 52 WEEKS[10]

About MSQoL[8,11]

- The Migraine-Specific Quality of Life Questionnaire is a widely used, validated, disease/migraine-specific 14-item tool. It measures the extent to which migraine has an impact on a patient's daily functioning across 3 domains:
  - Restrictive Role Function (7 items on how migraine limits daily activities; eg, reduced time with family, at leisure, at work)
  - Preventive Role Function (4 items on how migraine prevents daily activities; eg, canceled activities, help with routine tasks)
  - Emotional Function (3 items on emotions associated with migraine; eg, frustration, burden, fear)
- MSQoL scores are determined via a standardized calculation using the point total of each respective domain; the MSQoL was administered at baseline and at weeks 12, 24, 36, and 52

MSQoL scores at basel

The mean (SD) MSQoL s … l Function, and were consistent across the 3 e…

Limitation

These data are from an e… d may represent chance findings. Open-l… ed generalizability. Comparisons should no…

MSQoL=Migraine-Specific Quality …

REFERENCES

SELECT IMPORTANT …

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INDICATIONS

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• acute treatment of migraine with or without aura

• preventive treatment of episodic migraine

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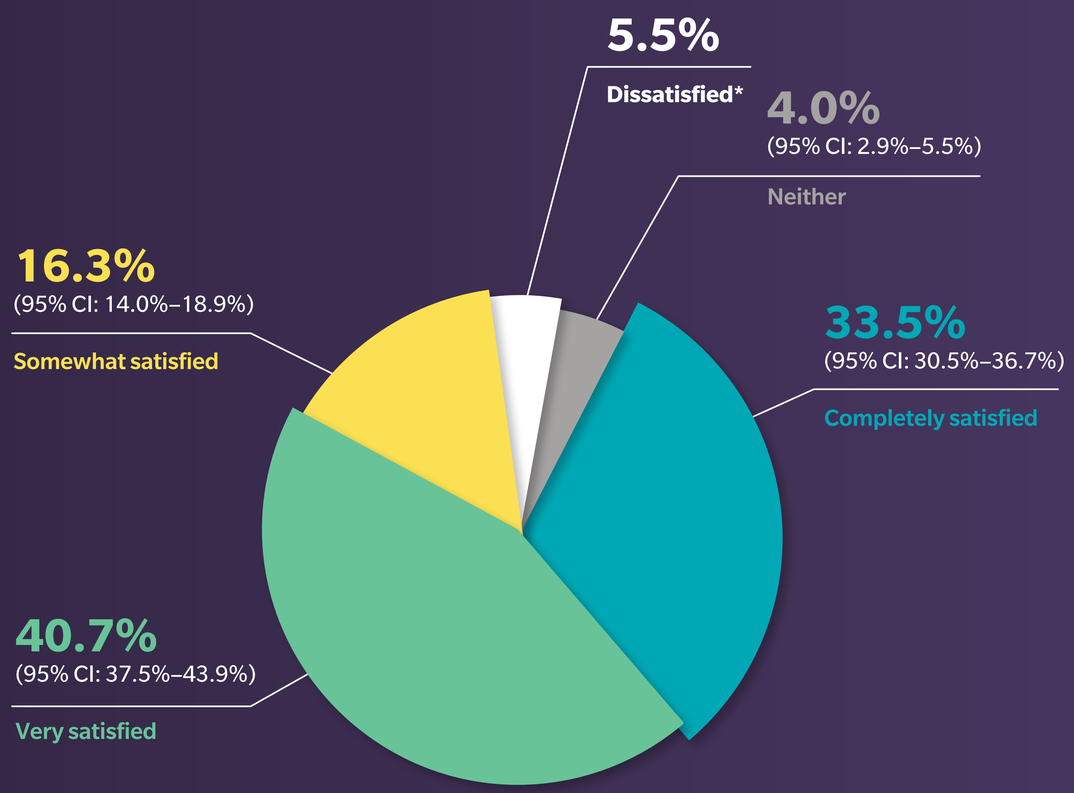
PATIENT SATISFACTION DATA FROM THE 52-WEEK OPEN-LABEL STUDY[12,13]

Prespecified exploratory endpoint



CI=confidence interval.

*Patients who were dissatisfied with treatment included patients who were somewhat dissatisfied (3.5% [95% CI: 2.5%–5.0%]), very dissatisfied (1.9% [95% CI: 1.2%–3.1%]), and completely dissatisfied (0.1% [95% CI: 0.0%–0.7%]).

74% of patients (655/883) were completely satisfied or very satisfied with rimegepant 75 mg following a 52-week study[12,13]

- 954 patients completed the 52-week study, of which 883 provided satisfaction data at this time point[12,13]
- Satisfaction was assessed with the Satisfaction with Medication questionnaire, which measures the patients' level of satisfaction with rimegepant in the study[12]

Limitation

These data are from an exploratory endpoint of the open-label long-term safety study, which was not powered to determine a treatment effect and may represent chance findings. Open-label extension studies tend to select patients who respond favorably to treatment, should be interpreted with caution, and may have limited generalizability. Comparisons should not be made across time points or patient cohorts. No conclusions can be drawn from this analysis.

REFERENCES

SELECT IMPORTANT SAFETY INFORMATION

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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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LONG-TERM SAFETY STUDIED UP TO 52 WEEKS

Phase 2/3, Open-Label Study Design[2,3,14]

Screening visit

- Adults with ≥1-year history of migraine*
- **4–18** moderate or severe attacks per month

Observation phase
4 weeks

Occurrence and severity of migraine attacks and utilization of migraine medication; served as baseline to measure the effect of treatment

Double-blind treatment phase
12 weeks†

R 1:1

- Rimegepant 75 mg, oral, EOD (n=370)
- Placebo, oral, EOD (n=371)

Open-label extension phase
up to 52 weeks

Rimegepant 75 mg EOD and PRN (as needed) on nonscheduled days

(max 1 tablet/day)
(N=603)‡

Lipton, American Headache Society 64th Annual Scientific Meeting (2022)

Safety endpoints[2]

AEs and clinical laboratory test evaluations, including liver function tests

Select exploratory endpoints[15]

Effect of rimegepant on preference of medication and satisfaction with medication, which were evaluated at weeks 12 and 52

AE=adverse event; CGI-C=Clinical Global Impression of Change; EOD=every other day; NSAID=nonsteroidal anti-inflammatory drug; ODT=orally disintegrating tablet; PRN=as needed.

*78 (21%) patients treated with rimegepant 75 mg and 95 (26%) patients treated with placebo had a history of chronic migraine, as assessed by the site principal investigator according to the *International Classification of Headache Disorders*, 3rd edition.[14]

†Permitted rescue medications during the 12-week double-blind treatment phase included triptans, NSAIDs, acetaminophen up to 1000 mg/day for a maximum of 2 consecutive days (including a fixed combination containing acetaminophen 250 mg, aspirin 250 mg, and caffeine 65 mg), baclofen, antiemetics, and muscle relaxants. Rimegepant 75 mg was not permitted as a rescue medication.[14]

‡This is the number of patients who were randomized and took at least one dose of rimegepant 75 mg. This study evaluated a rimegepant 75 mg tablet formulation that was found to be bioequivalent to rimegepant 75 mg ODT based on a phase 1 study.[2,4]

REFERENCES

SELECT IMPORTANT SAFETY INFORMATION

Warnings & Precautions (cont'd)

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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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Phase 2/3 Preventive Pivotal Study Design

Rimegepant 75 mg was evaluated for the preventive treatment of migraine in a multicenter, double-blind, randomized, placebo-controlled clinical trial of 747 total patients. The safety and tolerability of rimegepant 75 mg were further evaluated in a 52-week open-label extension phase that included 603 patients who completed the initial 12-week double-blind treatment phase.[3,14]

BASELINE OBSERVATION PHASE[14]
4 weeks

Patients had a history of 4–18 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.

TREATMENT PHASE[14]
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.[14]

This study evaluated a rimegepant 75 mg oral tablet formulation that was found to be bioequivalent to Nurtec ODT based on a phase 1 study.[4]

OPEN-LABEL EXTENSION PHASE[2,3]
52 weeks

Rimegepant 75 mg every-other-day preventive treatment
+
Rimegepant 75 mg as-needed acute treatment (n=603)

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 nonscheduled days as needed. Other permitted acute/rescue medications during the open-label extension phase included NSAIDs, acetaminophen, fixed combination acetaminophen/aspirin/caffeine, baclofen, antiemetics, and muscle relaxants. Triptans were permitted in the double-blind treatment phase but not the open-label extension phase. During the open-label extension, 10.9% of participants were using concomitant nonstudy preventive migraine medication.

Primary endpoint[14]

- Change from baseline in the mean number of total migraine days per month in weeks 9–12

Key secondary endpoint[14]

- Number of patients who had a ≥50% reduction in moderate or severe migraine days per month in weeks 9–12

Key inclusion criteria[14]

Eligible participants were men and women aged 18 years and older with at least a 1-year history of migraine with aura, migraine without aura, or chronic migraine, as defined by the *International Classification of Headache Disorders,* 3rd edition and an initial presentation of migraine before age 50 years. Participants also had to have at least 4, and not more than 18, migraine attacks of moderate or severe intensity per month (1 month defined as 4 weeks) over the 3-month period before the screening visit and at least 6 migraine days during the lead-in 4-week observation period. Participants had to be able to distinguish migraine attacks from attacks of tension-type and cluster headache. During the 12-week double-blind treatment phase of the study, participants were allowed to take 1 preventive migraine drug, excluding CGRP receptor antagonists and CGRP monoclonal antibodies, provided that the dose was stable for at least 3 months before the 4-week observation period and did not change during the observation period or the double-blind treatment phase. Participants were required to use 2 reliable means of contraception to avoid pregnancy throughout the study; women of childbearing potential had to have a negative pregnancy test (minimum sensitivity 25 IU/L or equivalent units of human chorionic gonadotropin) before receiving any study drug. Participants also had to have normal findings on medical and laboratory assessments; those with a clinical abnormality or laboratory parameters outside the reference range could be eligible for the study if the finding was judged not to be clinically significant by the investigator and did not introduce additional risk factors or interfere with the study procedures.

Key exclusion criteria[14]

Individuals were excluded if they had more than 18 headache days (migraine or nonmigraine) during the 4-week observation period or had a history of nonresponse to more than 2 drug categories for preventive treatment of migraine. Individuals were excluded if investigators believed they had a history or current evidence of any medical condition that would expose them to undue risk of a significant adverse event or interfere with assessments of safety or efficacy; if they had been treated for or showed evidence of alcohol or drug abuse within the past 12 months (48 weeks); if they had a history of drug or other allergy that made them unsuitable for participation; or if they had an electrocardiogram or laboratory test finding that raised safety or tolerability concerns.

Power of prevention without an injection[3,14]

- Patients taking rimegepant 75 mg (n=348) reduced MMDs by 4.3 vs 3.5 days for those on placebo at weeks 9–12 (n=347) (Δ-0.8, *P*=0.01) compared with baseline observation period*

Low incidence of adverse events[14]

- 2% of patients treated with rimegepant 75 mg discontinued due to adverse events in the pivotal prevention trial; rimegepant 75 mg was not associated with any serious treatment-related adverse events†

CGRP=calcitonin gene-related peptide; MMDs=monthly migraine days; NSAID=nonsteroidal anti-inflammatory drug.

*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.[14]

†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/incapacity; congenital anomaly/birth defect in the offspring of a subject who received rimegepant 75 mg; and others.[16]

SAFETY PROFILE OF LONG-TERM TREATMENT WITH NURTEC ODT EOD + PRN[2]

2.8%

OVERALL DISCONTINUATION RATE DUE TO AEs

Event, n (%)	Rimegepant 75 mg EOD + PRN (N=603)
Any AE	89 (14.8)
AEs REPORTED ≥2% OVERALL	
Upper respiratory tract infection	43 (7.1)
Nasopharyngitis	38 (6.3)
Back pain	26 (4.3)
Influenza	23 (3.8)
Urinary tract infection	19 (3.2)
Sinusitis	18 (3.0)
Arthralgia	15 (2.5)
AEs leading to discontinuation of rimegepant 75 mg	17 (2.8)
Serious AEs*	13 (2.2)
Serious AEs related to rimegepant 75 mg*	0

Exposure data[17]

Patients took a mean of 14.6 doses of rimegepant 75 mg per month in the open-label extension phase, with ~81% taking 16 or fewer tablets of rimegepant 75 mg per month

AE=adverse event; EOD=every other day; PRN=as needed.

*A serious adverse event was defined as 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/incapacity, congenital anomaly/birth defect in the offspring of a subject who received rimegepant, and others.[5]

REFERENCES

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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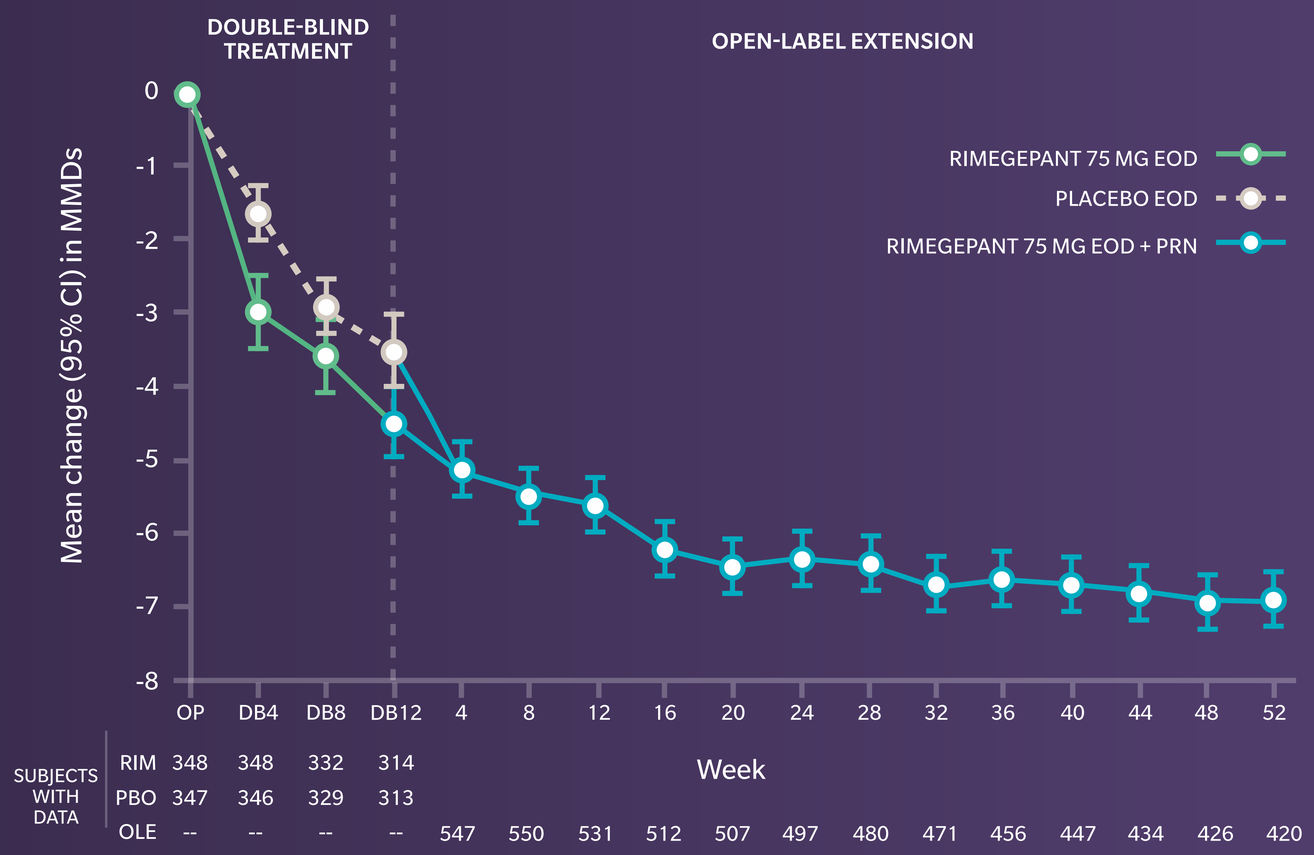
MEAN CHANGE FROM BASELINE IN MMDs OVER 16-MONTH TREATMENT PERIOD[18]

Prespecified Exploratory Endpoint From the Open-Label Extension Study

Limitation

These data are from an exploratory endpoint of the open-label long-term safety study, which was not powered to determine a treatment effect and may represent chance findings. Open-label extension studies tend to select patients who respond favorably to treatment, should be interpreted with caution, and may have limited generalizability. Comparisons should not be made across time points or patient cohorts. No conclusions can be drawn from this analysis.



- After 12 weeks, regardless of whether participants were randomized to receive rimegepant 75 mg or placebo during the double-blind phase, all patients received rimegepant 75 mg during the open-label phase[2]
- The mean (SD) number of MMDs during the observation period prior to double-blind treatment was 10.3 (3.2) for participants randomized to receive rimegepant 75 mg and 9.9 (3.0) for participants randomized to receive placebo[2]

CI=confidence interval; DB=double-blind; EOD=every other day; MMDs=monthly migraine days; OLE=open-label extension; OP=observation phase; PBO=placebo; PRN=as needed; RIM=rimegepant; SD=standard deviation.

REFERENCES

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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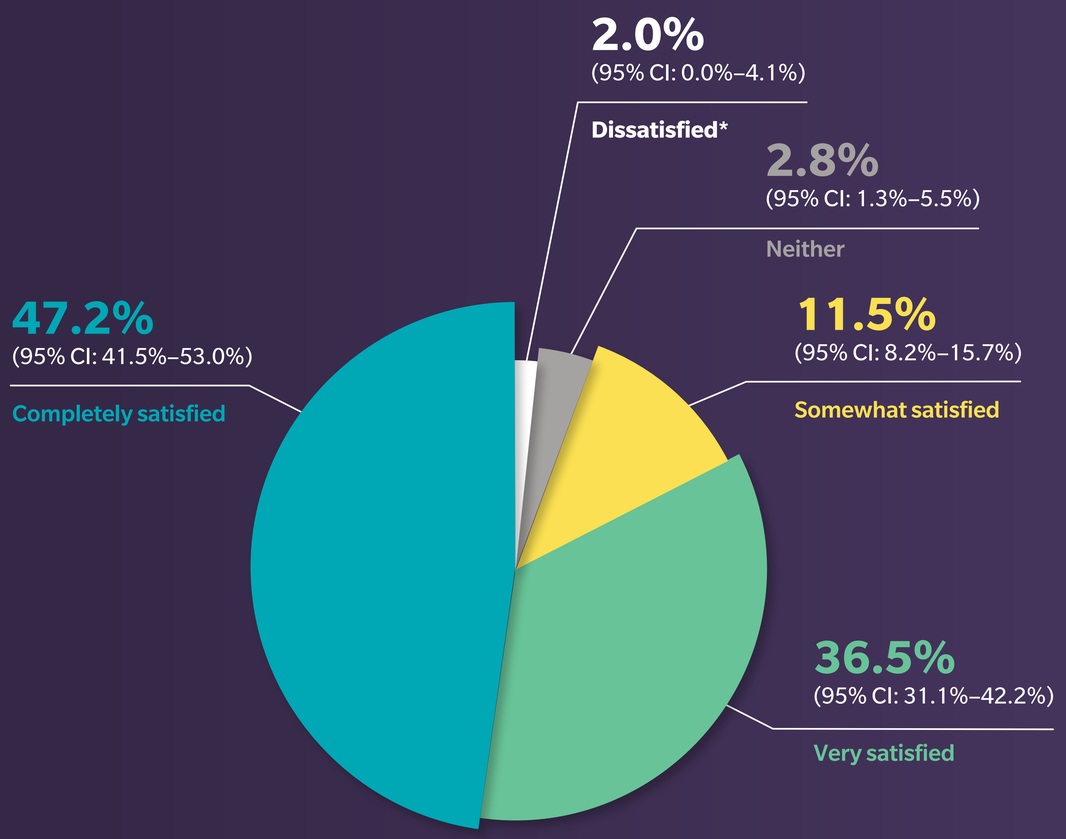
PATIENT SATISFACTION DATA FROM THE 52-WEEK OPEN-LABEL EXTENSION[15]

Prespecified exploratory endpoint



84% of patients (241/288) were completely satisfied or very satisfied with rimegepant 75 mg following a 52-week study[15,19]

- 420 patients completed the 52-week study, of which 288 provided satisfaction data at this time point[2,15,19]
- Satisfaction was assessed with the Satisfaction with Medication questionnaire, which measures the patients' level of satisfaction with rimegepant in the study[15]

Limitation

These data are from an exploratory endpoint of the open-label long-term safety study, which was not powered to determine a treatment effect and may represent chance findings. Open-label extension studies tend to select patients who respond favorably to treatment, should be interpreted with caution, and may have limited generalizability. Comparisons should not be made across time points or patient cohorts. No conclusions can be drawn from this analysis.

CI=confidence interval.

*Patients who were dissatisfied with treatment included patients who were somewhat dissatisfied (1.7% [95% CI: 0.6%–4.1%]), very dissatisfied (0% [95% CI: 0.0%–1.6%]), and completely dissatisfied (0.3% [95% CI: 0.0%–2.1%]).[19]

REFERENCES

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.

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

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PATIEN NSION[15]

47.2%
(95% CI: 41.5%–53.0%)
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patient cohorts.
[95% CI: 0.6%–4.1%]),
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References

References: 1. 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. **2.** Lipton RB, Kudrow D, Smith T, et al. Safety and tolerability of rimegepant every other day for preventive treatment of migraine plus as-needed for acute treatment of migraine: results from a 52-week, open-label extension study. Oral presentation at: American Headache Society 64th Annual Scientific Meeting; June 9-12, 2022; Denver, Colorado. **3.** Nurtec ODT. Package insert. Pfizer Inc. **4.** 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. **5.** Croop R, Goadsby PJ, Stock DA, et al. Efficacy, safety, and tolerability of rimegepant orally disintegrating tablet for the acute treatment of migraine: a randomised, phase 3, double-blind, placebo-controlled trial. *Lancet*. 2019;394(10200):737-745. **6.** Data on file. BHV3000-303 Clinical Study Report. Pfizer Inc. **7.** Croop R, Berman G, Kudrow D, et al. Long-term safety of rimegepant 75 mg for the acute treatment of migraine (study 201). Poster presented at: American Headache Society 62nd Annual Scientific Meeting; June 4-7, 2020; virtual. **8.** Supplement to: 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. **9.** True D, Mullin K, Croop R. Safety of rimegepant in adults with migraine and cardiovascular risk factors: analysis of a multicenter, long-term, open-label study. *Pain Ther.* 2024;13(5):1203-1218. **10.** L'Italien G, Thiry A, Croop R, et al. Acute migraine treatment with rimegepant 75 mg and health-related quality of life in migraine: results from a long-term, open-label safety study. Poster presented at: 19th International Headache Congress; September 5-8, 2019; Dublin, Ireland. **11.** Rendas-Baum R, Bloudek LM, Maglinte GA, Varon SF. The psychometric properties of the Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ) in chronic migraine patients. *Qual Life Res.* 2013;22(5):1123-1133. **12.** Turner I, Pavlovic JM, Lipton RB, et al. Patient preference, satisfaction, and improve Clinical Global Impression of Change with rimegepant 75 mg for the acute treatment of migraine: results from a long-term open-label safety study (study 201). Poster presented at: American Headache Society 62nd Annual Scientific Meeting; June 4-7, 2020; virtual. **13.** Data on file. BHV3000-201. Pfizer Inc. **14.** 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*. 2021;397(10268):51-60. **15.** Mullin K, Pavlovic JM, Hutchinson S, et al. Medication preference, satisfaction, and clinical improvement among adults receiving long-term treatment with rimegepant for migraine. Poster presented at: American Headache Society 64th Annual Scientific Meeting; June 9-12, 2022; Denver, Colorado. **16.** Data on file. BHV3000-303 Clinical Protocol. Pfizer Inc. **17.** Pavlovic JM, Turner I, Winner PK, et al. Long-term preventive and acute treatment of migraine with rimegepant improves health related quality of life. Poster presented at: American Headache Society 64th Annual Scientific Meeting; June 9-12, 2022; Denver, Colorado. **18.** Ailani J, Kudrow D, Smith T, et al. Effects of long-term rimegepant 75 mg on monthly migraine days. Poster presented at: American Headache Society 64th Annual Scientific Meeting; June 9-12, 2022; Denver, Colorado. **19.** Data on file. BHV3000-305-065. Pfizer Inc.

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