For the preventive treatment of episodic migraine in adults

Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

WITH NURTEC ODT, PATIENTS CAN EXPERIENCE EFFECTIVE MIGRAINE PREVENTION WITH EVERY-OTHER-DAY DOSING[1-4]

MONTHLY MIGRAINE DAY (MMD) REDUCTION PRIMARY ENDPOINT

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*=.01) compared to baseline observation period.[1,*]

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

SELECT IMPORTANT SAFETY INFORMATION

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

Warnings and Precautions: 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.

Adverse Reactions: The most common adverse reactions were nausea (2.7% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo) and abdominal pain/dyspepsia (2.4% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo). Hypersensitivity, including dyspnea and rash, occurred in less than 1% of patients treated with Nurtec ODT.

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PROVEN EFFECTIVE ***AT REDUCING MONTHLY MIGRAINE DAYS***

In a pivotal clinical trial, patients taking Nurtec ODT every other day demonstrated **significant reductions in mean monthly migraine days (MMDs)**[1,2]

-4.3
MMDs

Reduced MMDs by 4.3

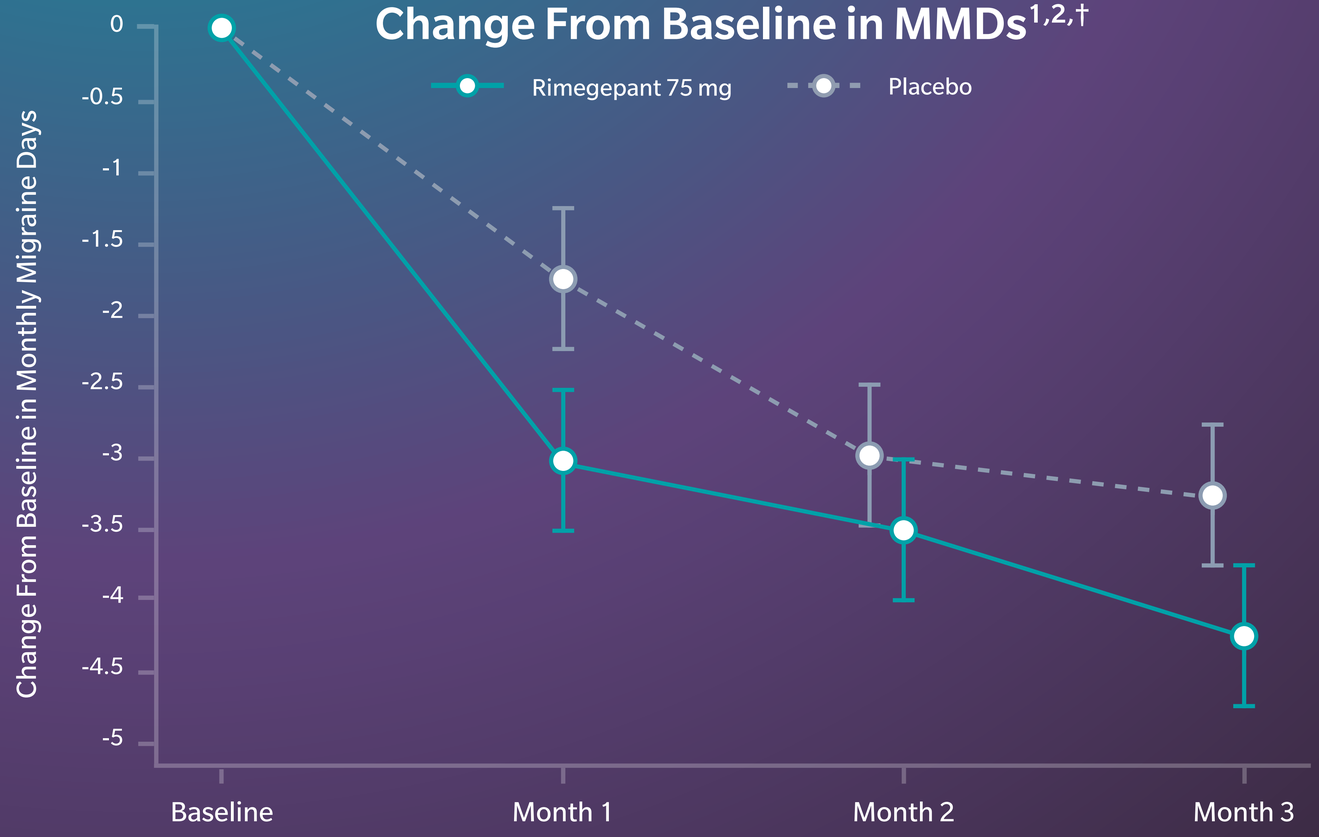
- Patients taking rimegepant 75 mg (n=348) reduced MMDs by 4.3 vs 3.5 days for those on placebo at Weeks 9-12 (n=347) (Δ-0.8, *P*=.01) (primary endpoint)[1,2,*]

49%
OF PATIENTS

Reduced Moderate-to-Severe MMDs by ≥50%

- 49% of patients taking rimegepant 75 mg (171/348) reduced moderate-to-severe MMDs by ≥50% vs 42% (144/347) of those on placebo (Δ8.0%, *P*=.044) (secondary endpoint)[1,2,*]

Change From Baseline in MMDs[1,2,†]



STUDY DESIGN

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

†Least-square means and 95% confidence intervals are presented. Baseline MMDs during the 4-week observation period were 10.3 for patients treated with Nurtec ODT and 9.9 for placebo-treated patients.[1,2]

SELECT IMPORTANT SAFETY INFORMATION

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 breastmilk 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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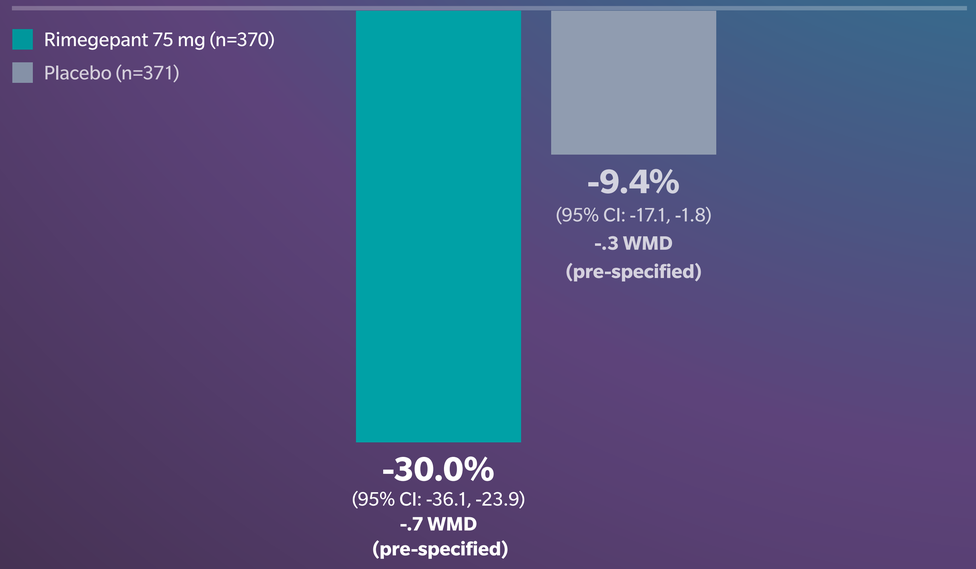
CHANGE FROM BASELINE IN MIGRAINE DAYS AT WEEK 1 AND MONTH 1[2,5]

Week 1[5]

Change From Baseline in Weekly Migraine Days (WMDs) at Week 1 Exploratory Post Hoc Analysis

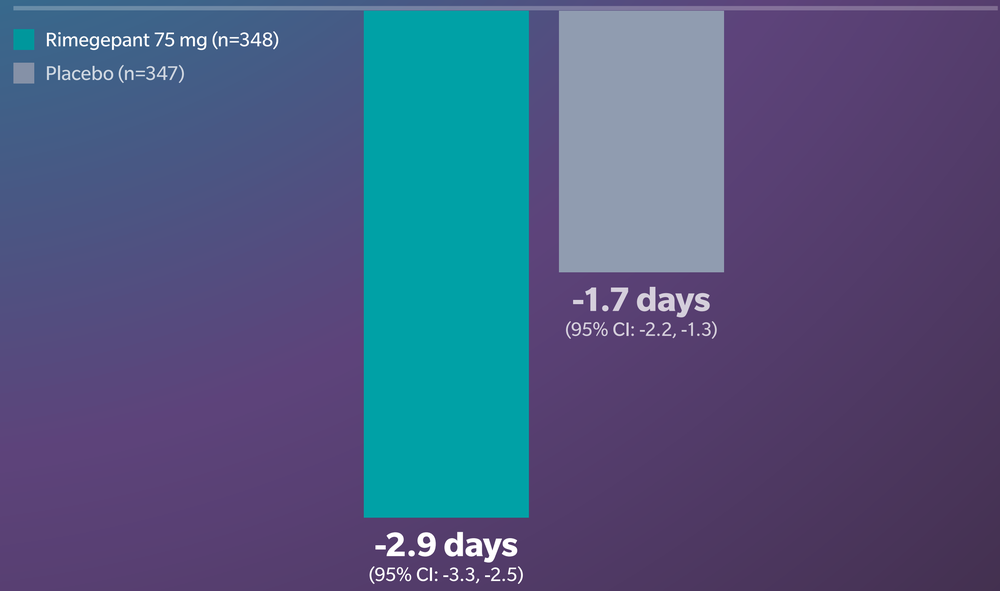


Limitations: This analysis was not tested in hierarchical order or adjusted for multiplicity. Results could represent chance findings.

Exploratory analysis. Patients had ≥1 day of efficacy data in the observation period and in the first week of the double-blind treatment period; weekly migraine frequency in the observation period was computed using the number of migraine days of the 4-week period prorated to 7 days.[5]

Weeks 1-4[2]

Change From Baseline in MMDs in Weeks 1-4 Select Secondary Endpoint



Nominal *P* value due to failure of a prior prespecified endpoint in hierarchical testing structure.[2]

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.[2]

STUDY DESIGN

SELECT IMPORTANT SAFETY INFORMATION

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

Warnings and Precautions: 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.

Adverse Reactions: The most common adverse reactions were nausea (2.7% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo) and abdominal pain/dyspepsia (2.4% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo). Hypersensitivity, including dyspnea and rash, occurred in less than 1% of patients treated with Nurtec ODT.

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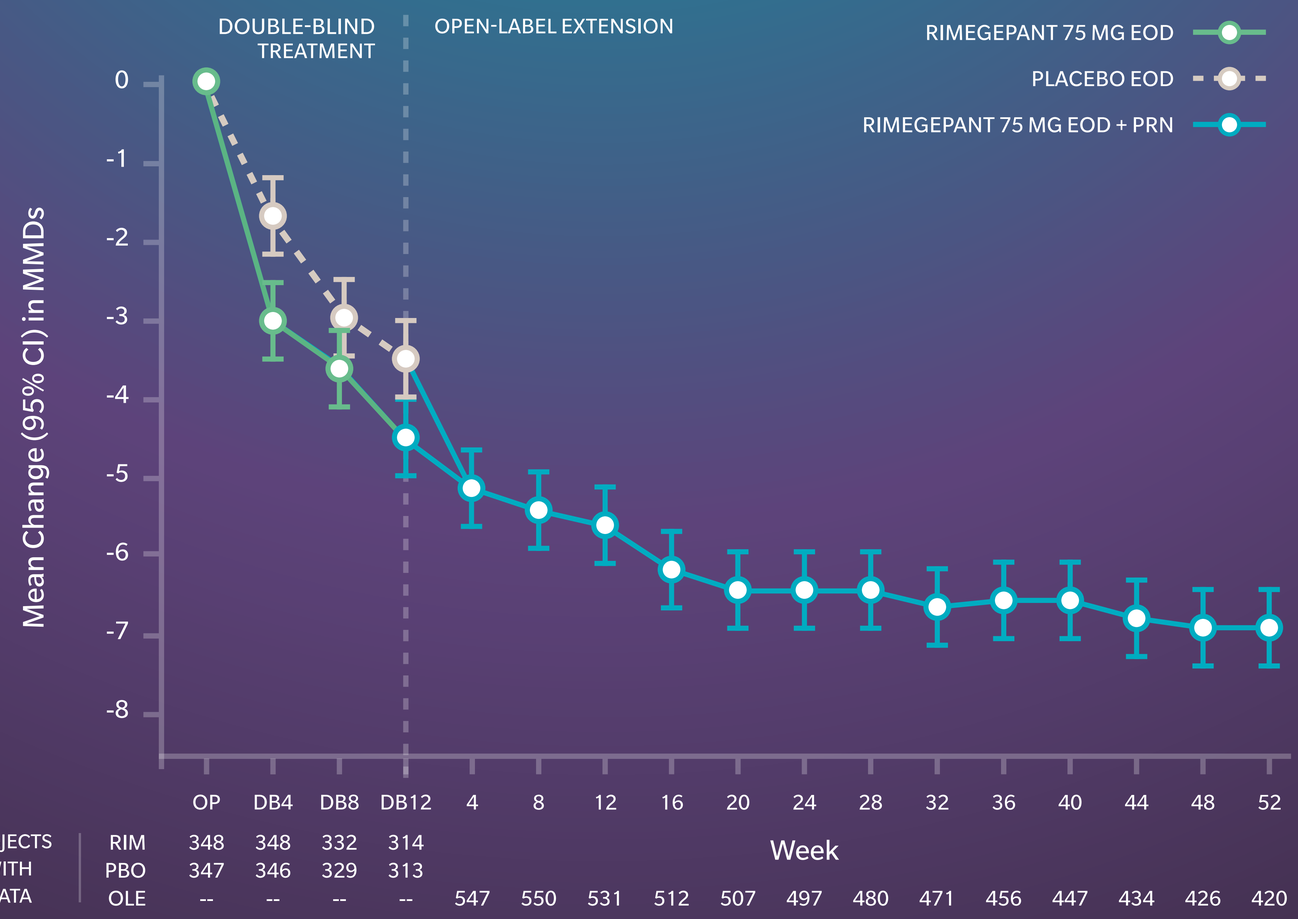
MEAN CHANGE FROM BASELINE IN MMDs OVER 16-MONTH TREATMENT PERIOD[3]

Prespecified Exploratory Endpoint From the Open-Label Extension Study[3]



Limitations: These analyses were not tested in hierarchical order or adjusted for multiplicity. Open-label studies tend to select for patients who respond favorably to treatment. Results could represent chance findings.

This was an open-label extension phase of a 12-week, phase 2/3, randomized, double-blind, placebo-controlled study of rimegepant 75 mg every other day (EOD) for preventive treatment of migraine. Patients who completed the 12-week double-blind treatment phase could continue to the 52-week open-label extension phase. During the open-label extension phase, patients could take 1 rimegepant 75 mg once EOD for preventive treatment of migraine on scheduled dosing days and 1 rimegepant 75 mg as needed for acute treatment of migraine on a nonscheduled dosing day.[6]

STUDY DESIGN

Patients should not take more than 75 mg of rimegepant per day, as the safety of using more than 18 doses in a 30-day period has not been established.[1]

DB=double-blind; OLE=open-label extension; OP=observation period; PBO=placebo; PRN=as needed; RIM=rimegepant.

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Warnings and Precautions: 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.

Adverse Reactions: The most common adverse reactions were nausea (2.7% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo) and abdominal pain/dyspepsia (2.4% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo). Hypersensitivity, including dyspnea and rash, occurred in less than 1% of patients treated with Nurtec ODT.

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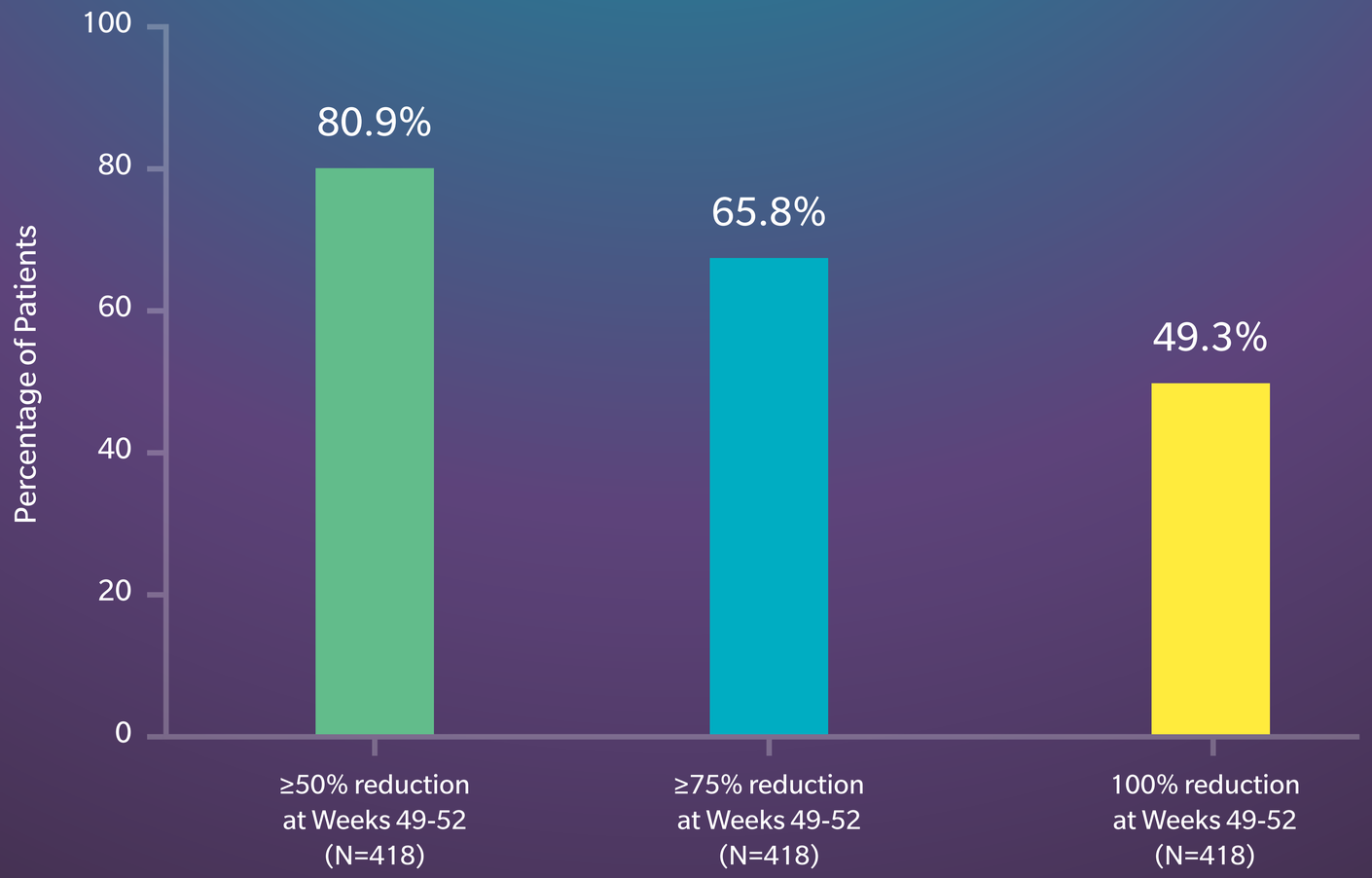
PERCENTAGE OF PATIENTS WITH REDUCTIONS IN MODERATE-TO-SEVERE MMDs FROM BASELINE DURING WEEKS 49-52[4]

Post Hoc Analysis From Prespecified Exploratory Endpoint: Change From Baseline in Moderate-to-Severe MMDs Over 1 Year From the Open Label Extension Study[4]



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This was an open-label extension phase of a 12-week, phase 2/3, randomized, double-blind, placebo-controlled study of rimegepant 75 mg every other day (EOD) for preventive treatment of migraine. Patients who completed the 12-week double-blind treatment phase could continue to the 52-week open-label extension phase. During the open-label extension phase, patients could take 1 rimegepant 75 mg once EOD for preventive treatment of migraine on scheduled dosing days and 1 rimegepant 75 mg as needed for acute treatment of migraine on a nonscheduled dosing day.[6]

STUDY DESIGN

SELECT IMPORTANT SAFETY INFORMATION

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 breastmilk 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 HAS A WELL-ESTABLISHED SAFETY PROFILE[1,2,7-11]

The most common adverse events with preventive treatment in the pivotal trial were nausea (Nurtec ODT 2.7% vs placebo 0.8%) and abdominal pain/dyspepsia (Nurtec ODT 2.4% vs placebo 0.8%)[1]

2%

2% of patients discontinued due to adverse events in the pivotal prevention trial[2]

0%

Nurtec ODT was not associated with any serious treatment-related adverse events[2,*]

STUDY DESIGN

*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.[11]

Safety profile demonstrated in the open-label extension study (OLE)

- **Long-term safety was assessed in an open-label extension study** that included 603 patients who were treated for up to 1 year[7]
- **Constipation incidence ranged from 1.1% with every-other-day dosing over 12 weeks in the double-blind study to 1.5% with every-other-day plus as-needed use over 52 weeks in the open-label study[8]**

Additional considerations for your patients who may benefit from Nurtec ODT

- **No restrictions** for patients taking oral contraceptives or antidepressants[1,9]
- **Not contraindicated** in patients with stable cardiovascular disease or risk factors[1]
- **~11-hour half-life** may facilitate rapid reduction or elimination of drug exposure, which may be helpful in case of an adverse event or when considering family planning[2]
- Lactation study demonstrated low breastmilk transfer, with a relative infant dose of <1% of the maternal weight-adjusted dose and a milk-to-plasma ratio of 0.20
  - There are no data on the effects of rimegepant 75 mg on a breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Nurtec ODT and any potential adverse effects on the breastfed infant from Nurtec ODT or from the underlying maternal condition[1,10]

SELECT IMPORTANT SAFETY INFORMATION

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INDICATIONS

Nurtec ODT is indicated in adults for the:
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FOR PREVENTIVE TREATMENT OF EPISODIC MIGRAINE IN ADULTS: ONE 75 MG NURTEC ODT EVERY OTHER DAY[1]

One simple 75 mg dosage strength in an ODT[1]

- No titration and no loading dose
- No injection, injection-site pain, or refrigeration
- No water needed, can be taken with or without food

For your patients who prefer an oral treatment to an injection, choose ***NURTEC ODT***

Patients don't have to take a daily pill for effective prevention

- Every-other-day dosing significantly reduces monthly migraine days[1-4]
- In the open-label extension phase of the prevention trial, breakthrough migraine attacks occurred at the same frequency on dosing vs non-dosing days[12,*]

STUDY DESIGN

*The frequency of moderate or severe migraine days was consistent for scheduled and nonscheduled days; on scheduled and nonscheduled dosing days over 52 weeks, mean (SD) moderate or severe monthly migraine days were 1.4 (1.71) and 1.4 (1.63), respectively.[12]

SELECT IMPORTANT SAFETY INFORMATION

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

Warnings and Precautions: 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.

Adverse Reactions: The most common adverse reactions were nausea (2.7% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo) and abdominal pain/dyspepsia (2.4% in patients who received Nurtec ODT compared to 0.8% in patients who received placebo). Hypersensitivity, including dyspnea and rash, occurred in less than 1% of patients treated with Nurtec ODT.

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CHOOSE NURTEC ODT FOR YOUR PATIENTS WHO NEED AN EFFECTIVE PREVENTIVE TREATMENT

SIGNIFICANT REDUCTION IN MONTHLY MIGRAINE DAYS[1,2]

THE ONLY GEPANT COMPARED TO AN INJECTABLE CGRP mAb IN A HEAD-TO-HEAD STUDY[13]

A WELL-ESTABLISHED SAFETY PROFILE OVER 64 WEEKS[1,2,7]

ONE 75 MG ODT TAKEN EVERY OTHER DAY[1]

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

Acute treatment is one 75 mg ODT taken as needed. 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 ~95% COMMERCIAL COVERAGE*

*Managed Markets Insights & Technology LLC as of [7/8/2024].

CGRP=calcitonin gene-related peptide; mAb=monoclonal antibody.

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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 breastmilk 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:
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- preventive treatment of episodic migraine

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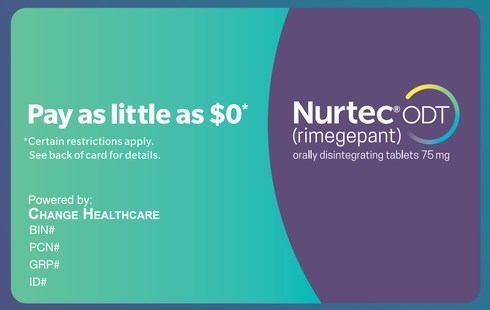
#1
PRESCRIBED MIGRAINE TREATMENT IN ITS CLASS
SINCE 8/6/21*

*Per IQVIA as oral brand in class (oral CGRP receptor antagonists); number one prescribed and number one in new prescriptions, since 8/6/21. Data current as of 3/31/24.



Nurtec® ODT (rimegepant) orally disintegrating tablets 75 mg

~95% COMMERCIAL COVERAGE†

Nurtec ODT has ~95% commercial coverage and eligible patients may pay as little as $0 per month with the copay 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.

†Managed Markets Insights & Technology LLC as of [7/8/2024].

INDICATIONS

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- preventive treatment of episodic migraine

IMPORTANT SAFETY INFORMATION

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Please see full Prescribing Information.

References: 1. Nurtec ODT. Package insert. Pfizer Inc. **2.** 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. **3.** Data on File. RIM 305-15. Pfizer Inc. **4.** Data on File. RIM 305-55. Pfizer Inc. **5.** Lipton RB, Croop R, Jensen CM, et al. Rapid decrease in migraine days with rimegepant: results from a post hoc analysis of a phase 2/3, randomized, double-blind, placebo-controlled trial. Poster presented at: Virtual Annual Scientific Meeting of the American Headache Society; 2021. **6.** 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. doi:10.1016/S0140-6736(20)32544-7. **7.** 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. **8.** Data on File. BHV300-305. Pfizer Inc. **9.** Baskin SM, Buse DC, Jensen CM, et al. Rimegepant 75 mg is safe and well tolerated for the acute treatment of migraine in adults using selective serotonin reuptake inhibitors and other antidepressants: results from a long-term open-label safety study (Study 201). Poster presented at: Virtual Annual Scientific Meeting of the American Headache Society; 2020. **10.** Baker TE, Croop R, Kamen L, et al. Human milk and plasma pharmacokinetics of single-dose rimegepant 75 mg in healthy lactating women. *Breastfeeding Medicine*. 2022;17(3):277-282. **11.** Data on File. BHV3000-303. Pfizer Inc. **12.** Data on File. RIM164. **13.** 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. **14.** Blumenfeld AM, Varon SF, Wilcox TK, et al. Disability, HRQoL and resource use among chronic and episodic migraineurs: results from the International Burden of Migraine Study (IBMS). *Cephalalgia*. 2011;31(3):301-315. doi:10.1177/0333102410381145 **15.** Headache Classification Committee of the International Headache Society. The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1–211. Pfizer Inc. **16.** Goadsby PJ, Evers S. International Classification of Headache Disorders - ICHD-4 alpha. *Cephalalgia*. 2020;40(9):887-888. doi:10.1177/0333102420919098

July 2024. PP-NNT-USA-3583.

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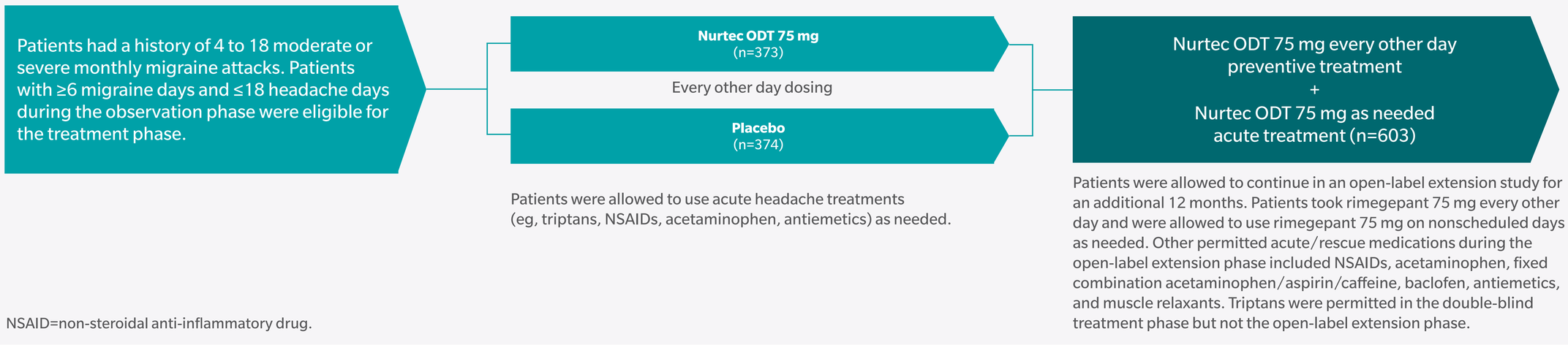
Preventive Study Design

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. The safety and tolerability of rimegepant 75 mg was further evaluated in a 52-week open-label extension study that included 603 patients who completed the initial 12-week, double-blind treatment phase.[2,7]



NSAID=non-steroidal anti-inflammatory drug.

Inclusion Criteria[2]

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.

Exclusion Criteria[2]

Individuals were excluded if they had more than 18 headache days (migraine or non-migraine) 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.

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MIGRAINE CLASSIFICATION BY FREQUENCY

~94%[14]

of patients have episodic migraine[15,16]

- Headache occurring on **fewer than 15 days a month over the last 3 months,** which on some days is migraine
- Does not meet diagnostic criteria for chronic migraine

~6%[14]

of patients have chronic migraine[15]

- Headache occurring on **≥15 days a month for >3 months**
- Headaches have features of migraine on ≥8 days a month

Nurtec ODT is indicated for the preventive treatment of episodic migraine in adults, not for chronic migraine.[1]