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*<.001); and 35.1% achieved freedom from most bothersome symptom (MBS) vs 26.8% on placebo (*P*=.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*<.0001).[1-3]

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 reaction was nausea (2% in patients who received Nurtec ODT compared to 0.4% 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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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

1
HOUR
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*<.001) **(co-primary endpoint)**[1]
- **35.1%** achieved freedom from most bothersome symptom (MBS) vs 26.8% on placebo; Δ8.3* (*P*=.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*<.001) **(select secondary endpoint)**[1]
- **38.1%** of patients returned to normal function vs 25.8% on placebo; Δ12.3%* (*P*<.001) **(select secondary endpoint)**[1]

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*=.0314) **(select secondary endpoint)**[2,3]
- **22.3%** had returned to normal function vs 15.8% on placebo; Δ6.4%* (*P*=.0025) **(select secondary endpoint)**[2,3]

STUDY DESIGN

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

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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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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*<.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]

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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-ESTABLISHED SAFETY PROFILE

Generally well tolerated

- The most common adverse event (AE) with acute treatment was nausea (Nurtec ODT 2%; placebo 0.4%)[1]
- Nurtec ODT was not associated with serious adverse events, and <3% of patients discontinued due to adverse events[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]

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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-ESTABLISHED 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 ~95% COMMERCIAL COVERAGE*

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

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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 3/31/24.

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~95% COMMERCIAL COVERAGE

Nurtec 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.

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Please see 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.

July 2024. PP-NNT-USA-3447.

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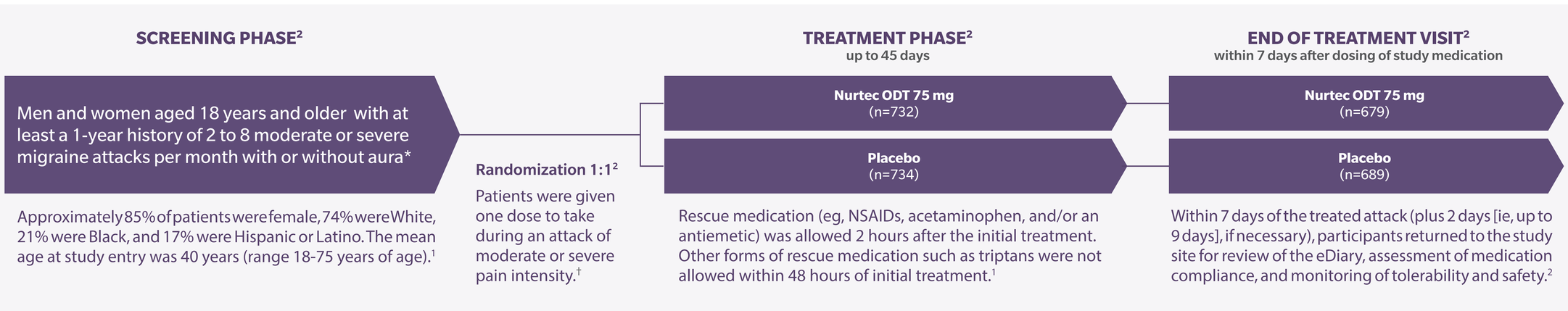
Acute Study Design

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]



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]