Nurtec ODT (rimegepant)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Nurtec ODT
- **Generic name:** Rimegepant
- **Pharmacologic class:** Calcitonin gene-related peptide (CGRP) receptor antagonist
- **Strength and Formulation:** 75mg; orally-disintegrating tablets (ODT)
- **Manufacturer:** Biohaven Pharmaceuticals
- **How supplied:** ODT tabs—8
- **Legal Classification:** Rx

Nurtec ODT

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Indication

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

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Limitation of Use

- Not indicated for the preventive treatment of migraine

Dosage and Administration

- **75mg once (max daily dose)**
- The safety of treating more than 15 migraines in a 30-day period has not been established
- Use dry hands when opening blister pack
- Place ODT on tongue; can also be placed under tongue
- ODT will disintegrate in saliva so that it can be swallowed without additional liquid
- **Do not** store ODT outside the blister pack for future use

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Considerations for Special Populations

- **Pregnancy:** no adequate data on developmental risk
- **Nursing mothers**: no data on presence in human milk
- **Pediatric**: safety, effectiveness not established
- **Geriatrics**: studies did not include sufficient numbers of patients aged 65 years and over to determine if response is different
- **Hepatic impairment**: avoid use in severe impairment (Child-Pugh C)
- **Renal impairment**: avoid use in end-stage renal disease (CrCl<15mL/min)

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Warnings/Precautions

- Discontinue if **hypersensitivity reaction** occurs; treat appropriately
  - Severe hypersensitivity reactions have included dyspnea and rash, and can occur days after administration
- **Severe hepatic impairment** (Child-Pugh C) or ESRD (CrCl <15mL/min): avoid
- **Dialysis**: not studied

Interactions

- Potentiated by **strong CYP3A4 inhibitors** (eg, itraconazole); avoid concomitant use
- May be potentiated by **moderate CYP3A4, P-gp, or BCRP inhibitors**
- Avoid another dose of Nurtec ODT within 48hrs when used with moderate CYP3A4 inhibitors
- May be antagonized by **moderate or strong CYP3A inducers** (eg, rifampin); avoid concomitant use

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Adverse Reactions

- **Most frequent (incidence >1%)**: nausea
- **Other**: delayed serious hypersensitivity

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Mechanism of Action

- Rimegepant is a calcitonin gene-related peptide (CGRP) receptor antagonist
- CGRP is believed to play a key role in migraine pathophysiology

Pharmacokinetics

- Plasma protein binding: ~96%
- Metabolism: primarily metabolized by CYP3A4 and to a lesser extent by CYP2C9
- Elimination half-life: ~11 hours
- Excretion: fecal, renal

Clinical Trials

- Phase 3 randomized, double-blind, placebo-controlled trial
- Patients randomized to rimegepant 75mg (n=732) or placebo (n=734)
- Rescue meds (NSAIDs, acetaminophen, and/or antiemetic) allowed 2 hours after initial treatment
- Other forms of rescue meds (ie, triptans) not allowed within 48 hours of initial treatment
- Approx. 14% of patients were taking preventive meds at baseline (none that act on CGRP pathway)

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Clinical Trials

- Co-primary end points:
  - Percentage of patients with freedom from pain at 2 hours postdose; pain levels were assessed on a 4-point scale and pain freedom was defined as pain level of none
  - Percentage of patients with freedom from most bothersome symptom (MBS) at 2 hours postdose; MBS was reported as nausea, photophobia, or phonophobia at migraine onset

Clinical Trials

- Percentage of patients achieving headache pain freedom and MBS freedom 2 hours after a single dose was statistically significantly greater in patients who received rimegepant compared with those who received placebo
- **Pain free at 2 hours** (% responders): 21.2% with rimegepant vs 10.9% with placebo (difference: 10.3%; *P* <.001)
- **MBS free at 2 hours** (% responders): 35.1% with rimegepant vs 26.8% with placebo (difference 8.3%; *P* <.001)

Clinical Trials

- Statistically significant effects of rimegepant compared with placebo were demonstrated for the additional efficacy end points of **pain relief** (defined as a reduction in migraine pain from moderate or severe severity to mild or none) at 2 hours, **sustained pain freedom** 2 to 48 hours, **use of rescue medication** within 24 hours, and the percentage of patients reporting **normal function** at 2 hours after dosing (derived from a single item questionnaire, asking patients to select one response on a 4-point scale; normal function, mild impairment, severe impairment, or required bedrest)

Clinical Trials

- **Pain relief at 2 hours** (% responders): 59.3% with rimegepant vs 43.3% with placebo (difference: 16.1%; *P* <.001)
- **Sustained pain freedom 2-48 hours** (% responders): 13.5% with rimegepant vs 5.4% with placebo (difference: 8.0%; *P* <.001)
- **Use of rescue meds within 24 hours** (% responders): 14.2% with rimegepant vs 29.2% with placebo (difference:-15.0%; *P* <.001)
- **Percentage of patients reporting normal function at 2 hours**: 38.1% with rimegepant vs 25.8% with placebo (difference: 12.3%; *P* <.001)

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Clinical Trials

- Incidence of photophobia and phonophobia was reduced following administration of rimegepant as compared with placebo

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/nurtec-odt/