Shout Out:

M&N's Pizza

Bethesda, MD

Every so often you happen upon that book, artwork, shop, restaurant, hotel or museum that strikes a particular chord, and in the past we have used this magazine to give "shout outs" to those treasures and the people responsible for them. Be it a Croatian artist and his gallery in Dubrovnik, a particularly hospitable pub in Dublin or a friendly group of superb river guides in Missoula, Montana, we hope our own wonderful experiences may yield something positive for at least a portion of our readership as well.

For example, your editor has had a long-standing love affair with salsa (the sauce, not the music; unfortunately, he is not a very good dancer), and he has never tasted a finer salsa than the Chimayo Red made by Santa Fe Seasons, available at The Chile Shop at 109 E. Water Street in Santa Fe (and, thankfully, online from the shop at www.thechileshop.com).

The utility of this issue's shout-out is directly relevant to only a small but lucky portion of the magazine's readership, but its intent is also to celebrate merchants everywhere who take a particular pride in their product and interest in their patrons.

The metropolitan DC area where the editor of this magazine grew up has transformed into a largely amorphous blob replete with the same chain restaurants and fast-food establishments one can find virtually anywhere in this country or even abroad. Thankfully, however, there do persist a surprisingly high number of mom 'n pop establishments notable for their excellent service, wonderful food and devotion to the community they serve.

One such establishment is M&N's Pizza located on Del Ray Avenue in "old" Bethesda, a couple of miles from the NIH and a quick scooter ride from the editor's house. For seven years he and his family have enjoyed pizza, wings and gyros unparalleled in their pizza-related culinary experience, and over those years we have come to know the owners well and count them as friends.

Manoj and Nazaneen Mehta (the "M&Ns"), originally from New Delhi and Kabul, respectively, have been married 18 years. For over 16 of those years they have worked tirelessly together to develop a take-out and delivery joint that, while modest in appearance, consistently has served the best pizza around. The editor is a big pizza fan, and what M&N's offers is no less enticing than the single-slice pizzas of Brooklyn, Chicago, Ocean City (Maryland) and a variety of other far-flung sources whose wares he has sampled over the years.

As appealing as their pizza is the kindness and courtesy of the owners. Even on the busiest Friday night, with the food delivery drivers bunched at the door and waiting with obvious impatience, Manoj greets his regular customers by name and with genuine interest inquires how things go with them and their families. Nazaneen is usually too busy working in the back to make an appearance at the counter, but when she does, her invariably pleasant words and demeanor lend a quiet softness to the end of even the most hectic of days.

Evidence of the devotion their patrons have for this restaurant and its owners are the myriad of Christmas and Hanukkah greeting cards, thank you notes and family photos proudly displayed on the walls. People in the surrounding community – high-achieving people often not easily satisfied - *love* this place and these people.

If you are ever in the Bethesda area and have a craving for superb pizza, wings, gyros or a wide variety of offerings of eastern Mediterranean or Indian heritage, do yourself a favor and call M&N's. Trust me on this one - you will not be disappointed.

https://www.mandnspizza.com/

Nurtec® ODT
(rimegepant)
orally disintegrating tablets 75 mg

THE ONLY MEDICATION PROVEN TO TREAT & PREVENT MIGRAINES

Ellie W
Actual Nurtec ODT patient

Nurtec ODT can:

TREAT MIGRAINE ATTACKS
Take Nurtec ODT as soon as a migraine strikes to help stop pain and other symptoms.*

PREVENT MIGRAINES
Take Nurtec ODT every other day to get ahead of migraines and known triggers.

Ask your doctor about Nurtec ODT

& learn how you can get savings and support at **nurtec.com/savings**

*Light sensitivity, sound sensitivity, or nausea.

IMPORTANT SAFETY INFORMATION

Do not take Nurtec ODT if you are allergic to Nurtec ODT (rimegepant) or any of its ingredients.

Before you take Nurtec ODT, tell your healthcare provider (HCP) about all your medical conditions, including if you:
• have liver problems, • have kidney problems, • are pregnant or plan to become pregnant, • are breastfeeding or plan to breastfeed.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Nurtec ODT may cause serious side effects including allergic reactions, including trouble breathing and rash. This can happen days after you take Nurtec ODT. Call your HCP or get emergency help right away if you have swelling of the face, mouth, tongue, or throat or trouble breathing. This occurred in less than 1% of patients treated with Nurtec ODT.

The most common side effects of Nurtec ODT were nausea (2.7%) and stomach pain/indigestion (2.4%). These are not the only possible side effects of Nurtec ODT. Tell your HCP if you have any side effects.

WHAT IS NURTEC ODT?
Nurtec ODT orally disintegrating tablets is a prescription medicine that is used to treat migraine in adults. It is for the acute treatment of migraine attacks with or without aura and the preventive treatment of episodic migraine. It is not known if Nurtec ODT is safe and effective in children.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 or report side effects to Biohaven at 1-833-4Nurtec.

Please see a Brief Summary of the Prescribing Information on the following page.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

(For complete product information, see Full Prescribing Information.)

NURTEC® ODT (rimegepant) orally disintegrating tablets 75 mg, for sublingual or oral use

1 INDICATIONS AND USAGE

1.1 Acute Treatment of Migraine

NURTEC ODT is indicated for the acute treatment of migraine with or without aura in adults.

1.2 Preventive Treatment of Migraine

NURTEC ODT is indicated for the preventive treatment of episodic migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing for Acute Treatment of Migraine

The recommended dose of NURTEC ODT is 75 mg taken orally, 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.

2.2 Recommended Dosing for Preventive Treatment of Episodic Migraine

The recommended dosage of NURTEC ODT is 75 mg taken orally every other day.

4 CONTRAINDICATIONS

NURTEC ODT is contraindicated in patients with a history of hypersensitivity reaction to rimegepant, NURTEC ODT, or any of its components. Delayed serious hypersensitivity has occurred *[see Warnings and Precautions (5.1)]*.

5 WARNING AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including dyspnea and rash, have occurred with NURTEC ODT in clinical studies. Hypersensitivity reactions can occur days after administration, and delayed serious hypersensitivity has occurred. If a hypersensitivity reaction occurs, discontinue NURTEC ODT and initiate appropriate therapy *[see Contraindications (4)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

• Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Acute Treatment of Migraine

The safety of NURTEC ODT for the acute treatment of migraine in adults has been evaluated in a randomized, double-blind, placebo-controlled trial (Study 1) in 682 patients with migraine who received one 75 mg dose of NURTEC ODT *[see Clinical Studies (14)]*. Approximately 85% were female, 74% were White, 21% were Black, and 17% were Hispanic or Latino. The mean age at study entry was 40 years (range 18-75 years of age).

Long-term safety was assessed in an open-label extension study using a different oral dosage form of rimegepant. That study evaluated 1,798 patients, dosing intermittently for up to 1-year, including 1,131 patients who were exposed to rimegepant 75 mg for at least 6 months, and 863 who were exposed for at least one year, all of whom treated an average of at least two migraine attacks per month.

The most common adverse reaction in Study 1 was nausea (2% in patients who received NURTEC ODT compared to 0.4% of patients who received placebo).

Hypersensitivity, including dyspnea and severe rash, occurred in less than 1% of patients treated with NURTEC ODT *[see Contraindications (4) and Warnings and Precautions (5.1)]*.

Preventive Treatment of Episodic Migraine

The safety of NURTEC ODT for the preventive treatment of episodic migraine in adults has been established in a randomized, double-blind, placebo-controlled trial with an open-label extension (Study 2) using a different oral dosage form of rimegepant *[see Clinical Studies (14)]*. In the 12-week, double-blind treatment period, 370 patients with migraine received one 75 mg dose of rimegepant every other day. Approximately 81% were female, 80% were White, 17% were Black, and 28% were Hispanic or Latino. The mean age at study entry was 41 years (range 18-74 years of age). Long-term safety was assessed in an open-label extension study that included 603 patients who were treated for up to one year. Overall, 527 patients were exposed to rimegepant 75 mg for at least 6 months, and 311 were exposed for at least one year.

The most common adverse reactions (occurring in at least 2% of rimegepant-treated patients and at a frequency of at least 1% higher than placebo) in Study 2 were nausea (2.7% in patients who received rimegepant compared with 0.8% of patients who received placebo) and abdominal pain/dyspepsia (2.4% in patients who received rimegepant compared with 0.8% of patients who received placebo).

7 DRUG INTERACTIONS

7.1 CYP3A4 Inhibitors

Concomitant administration of NURTEC ODT with strong inhibitors of CYP3A4 results in a significant increase in rimegepant exposure. Avoid concomitant administration of NURTEC ODT with strong inhibitors of CYP3A4 *[see Clinical Pharmacology (12.3)]*.

Concomitant administration of NURTEC ODT with moderate inhibitors of CYP3A4 may result in increased exposure of rimegepant. Avoid another dose of NURTEC ODT within 48 hours when it is concomitantly administered with moderate inhibitors of CYP3A4 *[see Clinical Pharmacology (12.3)]*.

7.2 CYP3A Inducers

Concomitant administration of NURTEC ODT with strong or moderate inducers of CYP3A can result in a significant reduction in rimegepant exposure, which may lead to loss of efficacy of NURTEC ODT. Avoid concomitant administration of NURTEC ODT with strong or moderate inducers of CYP3A *[see Clinical Pharmacology (12.3)]*.

7.3 P-gp Inhibitors

Concomitant administration of NURTEC ODT with potent inhibitors of P-gp (e.g., amiodarone, cyclosporine, lapatinib, quinidine, ranolazine) may result in increased exposure of rimegepant. Avoid another dose of NURTEC ODT within 48 hours when it is concomitantly administered with potent inhibitors of P-gp *[see Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to NURTEC ODT during pregnancy. For more information, healthcare providers or patients are encouraged to contact: 1-877-366-0324, email nurtecpregnancyregistry@ppd.com, or visit nurtecpregnancyregistry@registry.com.

Risk Summary

There are no adequate data on the developmental risk associated with the use of NURTEC ODT in pregnant women. In animal studies, oral administration of rimegepant during organogenesis resulted in adverse effects on development in rats (decreased fetal body weight and increased incidence of fetal variations) at exposures greater than those used clinically and which were associated with maternal toxicity. The evaluation of developmental effects following oral administration of rimegepant throughout pregnancy and lactation was inadequate (see Data).

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. The estimated rate of major birth defects (2.2 to 2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy.

8.2 Lactation

The transfer of rimegepant into breast milk is low (< 1%). The effect of rimegepant on a breastfeeding infant or on milk production is unknown. 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.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

In pharmacokinetic studies, no clinically significant pharmacokinetic differences were observed between elderly and younger subjects. Clinical studies of NURTEC ODT did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

8.6 Hepatic Impairment

No dosage adjustment of NURTEC ODT is required in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment. Plasma concentrations of rimegepant were significantly higher in subjects with severe (Child-Pugh C) hepatic impairment. Avoid use of NURTEC ODT in patients with severe hepatic impairment *[see Clinical Pharmacology (12.3)]*.

8.7 Renal Impairment

No dosage adjustment of NURTEC ODT is required in patients with mild, moderate, or severe renal impairment. NURTEC ODT has not been studied in patients with end-stage renal disease and in patients on dialysis. Avoid use of NURTEC ODT in patients with end-stage renal disease (CLcr < 15 mL/min) *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

There is limited clinical experience with NURTEC ODT overdosage. Treatment of an overdose of NURTEC ODT should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. No specific antidote for the treatment of rimegepant overdose is available. Rimegepant is unlikely to be significantly removed by dialysis because of high serum protein binding *[see Clinical Pharmacology (12.3)]*.

Manufactured for:

Biohaven Pharmaceuticals, Inc.
New Haven, CT 06510 USA

Last modified: 04/18/2022

US-RIMODT-2200289

biohaven™ pharmaceuticals


Your special
moments
should never
be ruined
by migraine.
We have
your back,
no matter where
the trail leads you.
Migraineur
Magazine
www.migraineurmagazine.com/subscribe