

# » ARE YOUR PATIENTS TOO BUSY FOR BREAKTHROUGH MIGRAINES?

“I’m finally in  
control of my migraines  
...*most of*  
*the time.*”

– Samantha, 43-year-old  
marketing consultant

Prescribed preventive medication,  
which reduced migraine frequency from  
15/month to 7/month

Migraines still disrupt Samantha’s day,  
causing head pain, canceled meetings,  
and time away from her 3 kids

**INDICATION:** ZOMIG Nasal Spray is a serotonin (5-HT)<sub>1B/1D</sub> receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years and older.

**Limitations of Use:** Use ZOMIG Nasal Spray only after a clear diagnosis of migraine has been established. If a patient has no response to ZOMIG Nasal Spray treatment for the first migraine attack, reconsider the diagnosis of migraine before ZOMIG Nasal Spray is administered to treat any subsequent attacks. ZOMIG Nasal Spray is not indicated for the prevention of migraine attacks. Safety and effectiveness of ZOMIG Nasal Spray have not been established for cluster headache. ZOMIG Nasal Spray is not recommended in patients with moderate to severe hepatic impairment.

**Please see additional Important Safety Information throughout this piece  
and accompanying Full Prescribing Information.**

**Zomig<sup>®</sup> Nasal Spray**  
ZOLMITRIPTAN 2.5 mg  
5 mg

## WHY IS A COMPLETE TREATMENT PLAN NEEDED TO HELP PATIENTS LIKE SAMANTHA?

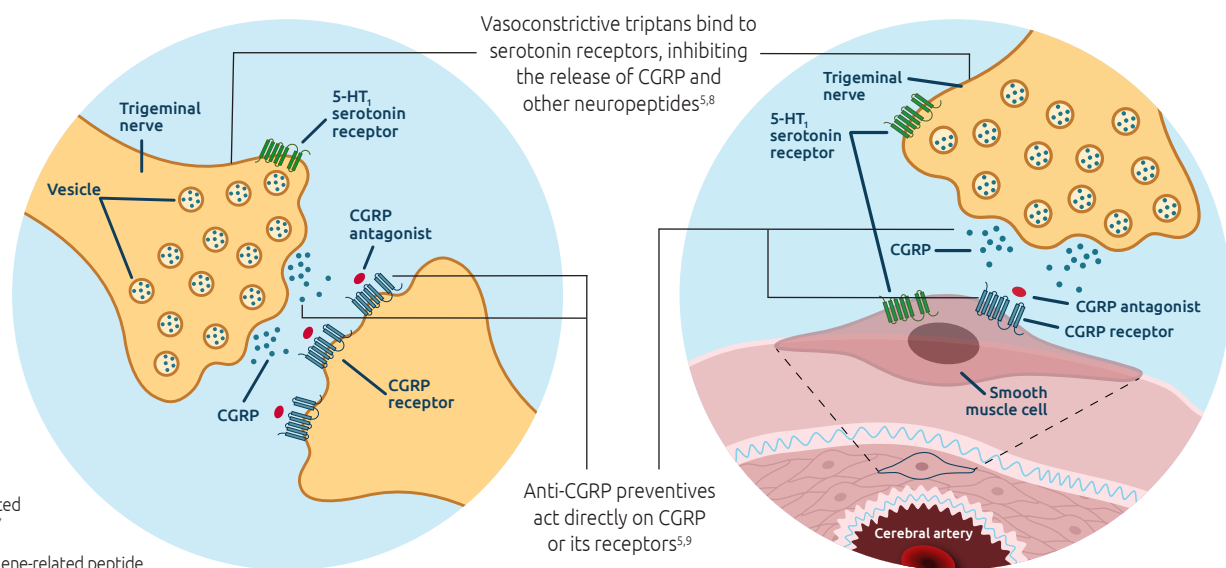
### EVEN IF PATIENTS TAKE A PREVENTIVE MEDICATION, MIGRAINES CAN STILL HAPPEN ANYTIME<sup>1,2</sup>

- In clinical trials, preventive and acute medications are often used together for comprehensive migraine control<sup>3,4</sup>
- Anti-CGRP medication may improve the efficacy of triptans<sup>5</sup>



### TRIPTANS AND ANTI-CGRP PREVENTIVES MAY WORK BEST TOGETHER<sup>5</sup>

Both treatments inhibit CGRP through different mechanisms<sup>6,7</sup>



Illustrations adapted from Durham PL.<sup>7</sup>

CGRP, calcitonin gene-related peptide.

### IMPORTANT SAFETY INFORMATION

#### Contraindications:

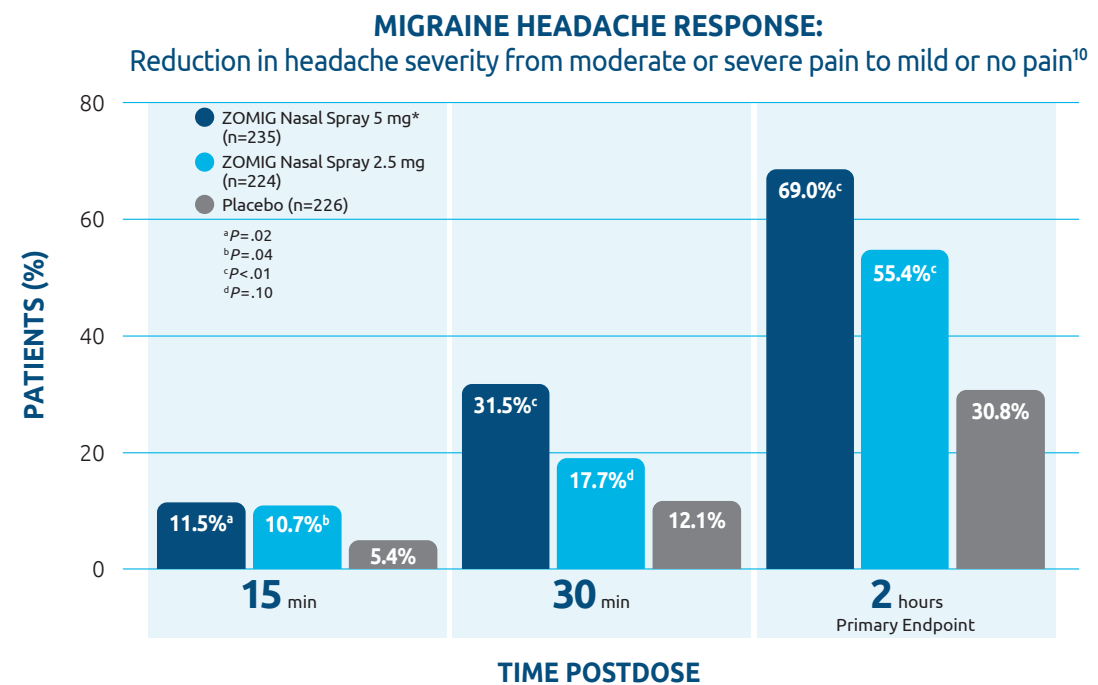
ZOMIG Nasal Spray is contraindicated in patients with: history of coronary artery disease (CAD) or coronary artery vasospasm or other significant underlying cardiovascular disease; Wolff-Parkinson-White Syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; recent (within 24 hours) use of another 5-HT<sub>1</sub> agonist (eg, another triptan), or ergot-type medication; current or recent (past 2 weeks) use of monoamine oxidase (MAO)-A inhibitor; known hypersensitivity to ZOMIG, ZOMIG-ZMT, or ZOMIG Nasal Spray

#### Warnings and Precautions:

- Myocardial ischemia, myocardial infarction, and Prinzmetal's Angina: Perform a cardiovascular evaluation in triptan-naïve patients who have multiple cardiovascular risk factors and if satisfactory, consider administering the first ZOMIG Nasal Spray dose in a medically supervised setting
- Arrhythmias: Discontinue ZOMIG Nasal Spray if these occur
- Sensations of tightness, pain, pressure in the chest, and heaviness in the precordium, throat, neck, and jaw commonly occur after treatment with 5-HT<sub>1</sub> agonists like ZOMIG Nasal Spray and are usually non-cardiac in origin. Perform a cardiac evaluation if these patients are at cardiac risk
- Cerebrovascular events: Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT<sub>1</sub> agonists, some resulting in fatalities. Discontinue ZOMIG Nasal Spray if any of these events occur

## WHEN BREAKTHROUGHS OCCUR, ZOMIG NASAL SPRAY MAY PROVIDE FAST RELIEF<sup>10</sup>

Even patients, like Samantha, who have been prescribed preventive medication may still need an acute treatment like ZOMIG Nasal Spray for breakthrough migraines.



From a multicenter, randomized, double-blind, double-dummy, placebo-controlled study of ZOMIG Nasal Spray 5 mg (n=235) and 2.5 mg (n=224) vs placebo (n=226) for the acute treatment of moderate or severe migraines in adults. **Primary endpoint was headache response at 2 hours. Secondary endpoints included measurements at 15 minutes, 30 minutes, 45 minutes, 1 hour, and 4 hours, the use of rescue medication, and pain-free outcomes.**<sup>10</sup>

Relief in as soon as



#### Efficacy was unaffected by<sup>11</sup>

- Migraine upon awakening
- Relationship to menses
- Migraine with nausea
- Migraine with aura
- Gender, age, or weight

NEARLY **70%** DID NOT NEED A SECOND 5-mg\* DOSE OR ADDITIONAL MEDICATION WITHIN 24 HOURS<sup>12</sup>

67.7% with ZOMIG Nasal Spray 5 mg / 60.7% with ZOMIG Nasal Spray 2.5 mg / 27.8% with placebo

\*The recommended starting dose of ZOMIG Nasal Spray is 2.5 mg.<sup>11</sup>

<sup>11</sup>Includes both patients who had a headache response at 2 hours and those who had no response to the initial dose. The trial protocol did not allow remedication within 4 hours postdose. P≤.0001 for all comparisons with placebo.<sup>12</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### Warnings and Precautions (continued):

- ZOMIG Nasal Spray may cause non-coronary vasospastic reactions, such as peripheral vascular ischemia, gastrointestinal vascular ischemia and infarction, splenic infarction, and Raynaud's syndrome. Discontinue ZOMIG Nasal Spray if any of these events occur
- Transient and permanent blindness and significant partial vision loss have been reported with the use of 5-HT<sub>1</sub> agonists

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**Zomig<sup>®</sup> Nasal Spray**  
ZOLMITRIPTAN  
2.5 mg  
5 mg



# ZOMIG NASAL SPRAY—TRUSTED FOR PATIENTS LIKE SAMANTHA FOR **MORE THAN 15 YEARS**

## ENSURE YOUR PATIENTS HAVE A COMPLETE TREATMENT PLAN WITH ZOMIG NASAL SPRAY

- Migraine relief in as soon as **15 minutes** for some patients using the 5-mg\* dose<sup>10</sup>
- Majority of patients did not need a second dose or additional medication **within 24 hours**<sup>12</sup>
- Nearly 36% of adult patients were pain free at 2 hours vs 6.4% with placebo<sup>10</sup>

\*The recommended starting dose of ZOMIG Nasal Spray is 2.5 mg.<sup>11</sup>

## IMPORTANT SAFETY INFORMATION (continued)

### Warnings and Precautions (continued):

- Overuse of acute migraine drugs may lead to exacerbation of headache. Detoxification may be necessary
- Serotonin syndrome may occur with triptans, including ZOMIG Nasal Spray, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, and MAO inhibitors. Discontinue ZOMIG Nasal Spray if serotonin syndrome is suspected
- Increase in blood pressure

### Adverse Reactions

The most common adverse reactions ( $\geq 5\%$  and  $>$  placebo) were:

- Adults: unusual taste, paresthesia, dizziness, and hyperesthesia
- Pediatrics: unusual taste

### Drug Interactions

- Cimetidine: If co-administered, limit the maximum single dose of ZOMIG Nasal Spray to 2.5 mg, not to exceed 5 mg in any 24-hour period

### Use in Specific Populations

- Pregnancy: Based on animal data, ZOMIG Nasal Spray may cause fetal harm
- Lactation: There are no data on the presence of zolmitriptan or its metabolites in human milk, effects on milk production, or on the breastfed infant
- Pediatrics: Safety and effectiveness of ZOMIG Nasal Spray in patients  $<12$  years of age have not been established

**To report SUSPECTED ADVERSE REACTIONS, contact Amneal Specialty, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**References:** 1. Migraine. Office on Women's Health. <https://www.womenshealth.gov/a-z-topics/migraine>. Updated April 1, 2019. Accessed May 31, 2019. 2. Diamond S, Wenzel R. *CNS Drugs*. 2002; 16(6):385-403. 3. Dodick DW, Ashina M, Brandes JL, et al. *Cephalalgia*. 2018;38(6):1026-1037. 4. Stauffer VL, Dodick DW, Zhang Q, Carter JN, Ailani J, Conley RR. *JAMA Neurol*. 2018;75(9):1080-1088. 5. Anti-CGRP migraine treatments: your questions answered. American Research Foundation. <https://americanmigraine.foundation.org/resource-library/anti-cgrp-migraine-treatments-your-questions-answered>. Published October 1, 2018. Accessed July 8, 2019. 6. Chan KY, Vermeersch S, de Hoon J, Villalón CM, MaassenVanDenBrink A. *Pharmacol Ther*. 2011;129(3):332-351. 7. Durham PL. *N Engl J Med*. 2004;350(11):1073-1075. 8. Negro A, Koverech A, Martelletti P. *J Pain Res*. 2018;11:515-526. 9. Pellesi L, Guerzoni S, Pini LA. *Clin Pharmacol Drug Dev*. 2017;6(6):534-547. 10. Data on file, Impax Laboratories, LLC. 11. ZOMIG Nasal Spray [package insert]. 12. Charlesworth BR, Dowson AJ, Purdy A, Becker WJ, Boes-Hansen S, Färkkilä M. *CNS Drugs*. 2003;17(9):653-667.

**Please see additional Important Safety Information throughout this piece and accompanying Full Prescribing Information.**



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**Eligible patients may save on their ZOMIG Nasal Spray prescription. Visit [ZNSBreakthrough.com](http://ZNSBreakthrough.com) for Terms, Conditions, and Eligibility Criteria.**

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ZOLMITRIPTAN 2.5 mg 5 mg