

ARE YOUR PATIENTS' MIGRAINES **ABOUT MORE THAN HEAD PAIN?**

“My migraines
are made of
*...more than
just pain.*”

— Phillip, 34-year-old
construction worker

Experiences troublesome symptoms,
such as photophobia, phonophobia, and
nausea with his migraines

Loses multiple work days per
month due to migraines



INDICATION: ZOMIG Nasal Spray is a serotonin (5-HT)_{1B/1D} 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[®] Nasal Spray
ZOLMITRIPTAN 2.5 mg
5 mg

ADDRESSING THE FULL BURDEN OF YOUR PATIENTS' MIGRAINES

TREATING THE FULL RANGE OF MIGRAINE SYMPTOMS WITH A SINGLE SPRAY

THE MAJORITY OF PATIENTS ARE MULTISYMPTOMATIC, REPORTING A RANGE OF SYMPTOMS BEYOND HEAD PAIN*1

PHOTOPHOBIA	NAUSEA	PHONOPHOBIA	SOMNOLENCE
92%	86%	82%	66%
			

It’s not just pain—patients need fast relief that covers a range of symptoms.

ZOMIG NASAL SPRAY MAY TREAT MORE THAN JUST HEAD PAIN²

PERCENTAGE OF PATIENTS WHO EXPERIENCED MEANINGFUL IMPROVEMENTS IN TROUBLESOME MIGRAINE SYMPTOMS AT 2 HOURS*2		
	ZOMIG Nasal Spray 5 mg†	Placebo
PHOTOPHOBIA	59.0%	27.1%
NAUSEA	62.2%	43.3%
PHONOPHOBIA	57.3%	24.9%
SOMNOLENCE	45.5%	25.0%

35.5% of patients were pain-free 2 hours after using ZOMIG Nasal Spray 5 mg compared with 6.4% for placebo (P=.0001)¹

*According to the baseline symptoms of 1372 migraine patients from 42 centers across 11 countries in a study evaluating treatment efficacy.¹

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-HT₁ 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-HT₁ 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-HT₁ agonists, some resulting in fatalities. Discontinue ZOMIG Nasal Spray if any of these events occur

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 improvement of associated headache symptoms (nausea, photophobia, phonophobia, and somnolence), pain-free outcomes, measurements at 15 minutes, and the use of rescue medication.¹²

*These endpoints were not analyzed for statistical significance.²

†The recommended starting dose of ZOMIG Nasal Spray is 2.5 mg.³

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-HT₁ agonists
- 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

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FAST FORWARD TO MIGRAINE RELIEF WITH ZOMIG NASAL SPRAY



RELIEF WITH LESS DELAY

- 11.5% of ZOMIG Nasal Spray 5 mg* patients achieved headache response within **15 minutes** vs 5.4% with placebo ($P=.02$)¹

The majority of patients had headache response at 2 hours (primary endpoint).¹

RELIEF IS JUST ONE SPRAY AWAY

- **Nearly 70%** did not need additional medication **within 24 hours**^{†2}
 - **67.7%** with the 5-mg dose
 - **60.7%** with the 2.5-mg dose
 - **27.8%** with placebo
- **Efficacy was unaffected by** migraine with nausea or aura; migraine upon awakening; relationship to menses; or gender, age, or weight³

*The recommended starting dose of ZOMIG Nasal Spray is 2.5 mg.³

[†]Secondary end point. 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 rescue medication within 4 hours postdose. $P \leq .0001$ for all comparisons with placebo.²

IMPORTANT SAFETY INFORMATION (continued)

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.

References: 1. Data on file, Impax Laboratories, LLC. 2. Charlesworth BR, Dowson AJ, Purdy A, Becker WJ, Boes-Hansen S, Färkkilä M. *CNS Drugs*. 2003;17(9):653-667. 3. ZOMIG Nasal Spray [package insert].

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ZOLMITRIPTAN 2.5 mg, 5 mg