

# PAIN FREE IS POSSIBLE FOR SOME ADOLESCENTS<sup>1</sup>

The first and only nasal spray approved for adolescent migraine patients (ages 12-17 years).<sup>2</sup>

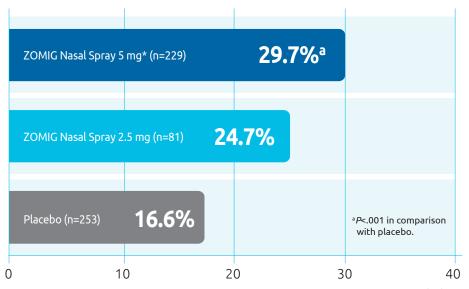


**Placebo challenge:** A 30-day placebo challenge run-in period was implemented. Patients treated a single migraine with 1 dose of single-blind placebo. Only patients who demonstrated a lack of response to placebo during the run-in period were randomized.<sup>3</sup>

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

From a multicenter, randomized, double-blind, parallel-group, placebo-controlled study of ZOMIG Nasal Spray 5 mg (n=229) and 2.5 mg (n=81) vs placebo (n=253) for the acute treatment of moderate or severe migraine in pediatric patients (ages 12-17 years). **Primary endpoint was no headache pain at 2 hours.**¹

PAIN FREE: Reduction in headache pain from severe or moderate pain to no pain<sup>1</sup>



PATIENTS WITH NO HEADACHE PAIN AT 2 HOURS POSTTREATMENT (%)1

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.

#### 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 administrating 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





# A SINGLE SPRAY MAY BE ALL MOST ADOLESCENTS NEED<sup>1</sup>



**Nearly 80%** of adolescent patients using ZOMIG Nasal Spray 5 mg\* **DID NOT** need to use a second dose or additional medications **within 24 hours** compared with 68.4% for placebo (P=.004)<sup>1</sup>

- 79.7% with ZOMIG Nasal Spray 5 mg
- 77.8% with ZOMIG Nasal Spray 2.5 mg

## **GETTING BACK TO NORMAL ACTIVITIES COULD BE A SPRAY AWAY**

At 4 hours, **71%** of patients returned to normal activities using either ZOMIG Nasal Spray 5 mg (P=.002) or 2.5 mg (P=.028) vs 57% for placebo.<sup>1</sup>

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From a multicenter, randomized, double-blind, parallel-group, placebo-controlled study of ZOMIG Nasal Spray 5 mg (n=229) and 2.5 mg (n=81) vs placebo (n=253) for the acute treatment of moderate or severe migraines in pediatric patients (ages 12-17 years). **Primary endpoint was no headache pain at 2 hours. Secondary endpoints included the use of rescue medication and the ability to perform normal activities.**¹

## **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
- 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.

References: 1. Data on file, Impax Laboratories, LLC. 2. FDA approves ZOMIG® (zolmitriptan) Nasal Spray for migraine in pediatric patients (ages 12-17) [press release]. Hayward, CA: PR Newswire; June 16, 2015. 3. ZOMIG Nasal Spray [package insert].

Please see additional Important Safety Information on reverse side and accompanying Full Prescribing Information.







Eligible patients may save on their ZOMIG Nasal Spray prescription. Visit ZNSSavings.com for Terms, Conditions, and Eligibility Criteria.