# FIRST TIME GENERIC APPROVAL

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| **Brand Name** | Zomig® |
| **Generic Name** | zolmitriptan |
| **Drug Manufacturer** | Amneal Pharmaceuticals |

## New Drug Approval

### TYPE OF CLINICAL UPDATE

First Time Generic - New Dosage Form

### FDA APPROVAL DATE

N/A

### LAUNCH DATE

FDB addition date – 1/22/2021

### REVIEW DESIGNATION

Type 3 - New Dosage Form, Standard

### TYPE OF REVIEW

New Drug Application (NDA): 021450

### DISPENSING RESTRICTIONS

N/A

## Overview

### INDICATION FOR USE

Zolmitriptan 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.

### MECHANISMS OF ACTION

Zolmitriptan binds with high affinity to human recombinant 5-HT1D and 5-HT1B receptors, and moderate affinity for 5- HT1A receptors. The N-desmethyl metabolite also has high affinity for 5-HT1B/1D and moderate affinity for 5-HT1A receptors. Migraines are likely due to local cranial vasodilatation and/or to the release of sensory neuropeptides (vasoactive intestinal peptide, substance P and calcitonin gene-related peptide) through nerve endings in the trigeminal system. The therapeutic activity of Zomig® for the treatment of migraine headache is thought to be due to the agonist effects at the 5-HT1B/1D receptors on intracranial blood vessels (including the arterio-venous anastomoses) and sensory nerves of the trigeminal system which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

### DOSE FORM AND STRENGTH

- Nasal spray: 2.5 mg and 5 mg

### DOSE & ADMINISTRATION

- Recommended starting dose: 2.5 mg.

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- Maximum single dose: 5 mg.
- May repeat dose after 2 hours if needed; not to exceed 10 mg in any 24- hour period.