

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Zomig®
<b>Generic Name</b>	zolmitriptan
<b>Drug Manufacturer</b>	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.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

## FIRST TIME GENERIC APPROVAL

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

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.