EMERGENCY OVERVIEW

Each Zolmitriptan orally disintegrating Tablet intended for oral administration contains Zolmitriptan and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

Identification of the product

Product name: Zolmitriptan orally disintegrating Tablet

Formula: C_{16}H_{21}N_{5}O_{2}

Chemical Name: (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone

Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India


Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319

Emergency Telephone No. Tel.: +91 79 6868100

Recommended use / Therapeutic Category Antimigraine
Restriction on Use / Contraindications
Zolmitriptan tablets are contraindicated in patients with:
- Ischemic coronary artery disease (angina pectoris, history of myocardial infarction, or documented silent ischemia), other significant underlying cardiovascular disease, or coronary artery vasospasm including Prinzmetal’s angina.
- Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders.
- History of stroke, transient ischemic attack (TIA), or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke.
- Peripheral vascular disease (PVD).
- Ischemic bowel disease.
- Uncontrolled hypertension.
- Recent use (i.e., within 24 hours) of another 5-HT1 agonist ergotamine-containing medication, or ergot-type medication (such as dihydroergotamine or methysergide).
- Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent use of a MAO-A inhibitor (that is within 2 weeks) Known hypersensitivity to zolmitriptan (angioedema and anaphylaxis seen).

Section 2. Hazard(s) Information

Dose and Administration
The recommended starting dose of zolmitriptan tablets is 1.25 mg or 2.5 mg. The 1.25 mg dose can be achieved by manually breaking the functionally-scored 2.5 mg tablet in half. The maximum recommended single dose of zolmitriptan tablets is 5 mg.

Adverse Effects
Most common adverse reactions (≥ 5% and > placebo) were neck/throat/jaw pain/tightness/pressure, dizziness, paresthesia, asthenia, somnolence, warm/cold sensation, nausea, heaviness sensation, and dry mouth.

Over Dose Effects
There is no experience with acute overdose of zolmitriptan. Clinical Study subjects who received single 50 mg oral doses of zolmitriptan commonly experienced sedation.

Contraindications
Zolmitriptan tablets are contraindicated in patients with:
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**Medical condition**

Do not take zolmitriptan if you:
- Have heart disease or a history of heart disease
- Have uncontrolled high blood pressure
- Have hemiplegic or basilar migraine (if you are not sure about this, ask your doctor)
- Have or had a stroke or problems with your blood circulation
- Have serious liver problems

Have taken any of the following medicines in the last 24 hours: other “triptans” like almotriptan (AXERT®$), eletriptan (RELPAX®$), frovatriptan (FROVA®$), naratriptan (AMERGE®$), rizatriptan (MAXALT®$), sumatriptan (IMITREX®$), sumatriptan/naproxen (TREXIMET®$); ergotamines like BELLERGAL-S®$, CAFERGOT®$ , ERGOMAR®$, MIGRAINE®$; dihydroergotamine like D.H.E. 45® or MIGRAL®; or methysergide (SANSERT®$). These medications have side effects similar to zolmitriptan. Have taken monoamine oxidase (MAO) inhibitors such as phenelzine sulfate (NARDIL®$) or tranylcypromine sulfate (PARNATE®$) for depression or other conditions within the last 2 weeks.
- Are allergic to zolmitriptan or any of its ingredients. The active ingredient is zolmitriptan. The inactive ingredients are listed at the end of this leaflet.

Tell your doctor about all the medicines you take or plan to take, including prescription and non-prescription medicines, supplements, and herbal remedies.
Tell your doctor if you are taking selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs), two types of drugs for depression or other disorders. Common SSRIs are CELEXA® (citalopram HBr), LEXAPRO® (escitalopram oxalate), PAXIL® (paroxetine), PROZAC® (fluoxetine), SYMYAX® (olanzapine/fluoxetine), ZOLOFT® (sertraline), SARAFEM® (fluoxetine) and LUVOX® (fluvoxamine). Common SNRIs are CYMBALTA® (duloxetine) and EFFEXOR® (venlafaxine). Your doctor will decide if you can take zolmitriptan with your other medicines.

Tell your doctor if you know that you have any of the following: risk factors for heart disease like high cholesterol, diabetes, smoking, obesity (overweight), menopause, or a family history of heart disease or stroke.

Tell your doctor if you are pregnant, planning to become pregnant, breastfeeding, planning to breastfeed, or not using effective birth control.

Pregnancy Comments
There are no adequate and well-controlled studies in pregnant women; therefore, zolmitriptan should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category
C

Section 3. Composition / information on ingredient
Safety Data Sheet
Zolmitriptan Orally Disintegrating Tablet

**Strength:** 2.5/5mg.  **Pack Size:** 30/90/100/1000 tablets per bottle for 2.5/5 mg
Unit dose blisters of 1X6 and 10X10 for 2.5 mg
Unit dose blisters of 1X3 and 10X10 for 5 mg  **Revision No.:** 02

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<td>Mannitol</td>
<td></td>
<td>69-65-8</td>
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<td>Microcrystalline cellulose</td>
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<td>Orange flavor</td>
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<td>NA</td>
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<tr>
<td>Polacrilin potassium</td>
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<tr>
<td>Sodium stearyl fumarate</td>
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**Section 4. First-aid measures**

**General**
- **Inhalation**
  Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
- **Contact with skin**
  Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
- **Contact with eyes**
  Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice
- **Ingestion**
  If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice

**Overdose Treatment**
There is no specific antidote to zolmitriptan. In cases of severe intoxication, intensive care procedures are recommended, including establishing and maintaining a patent airway, ensuring adequate oxygenation and ventilation, and monitoring and support of the cardiovascular system.

**Section 5. Fire-fighting measures**

<table>
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<tr>
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<th>Upper Flammable Limit</th>
<th>Lower Flammable Limit</th>
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<tr>
<td></td>
<td></td>
<td><strong>Lower Flammable Limit:</strong></td>
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</tr>
</tbody>
</table>
Extinguishing Media  Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Fire Fighting Procedure  As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Fire and Explosion Hazard  This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.

Section 6.  Accidental Release Measures

Spill Response  Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7.  Handling and Storage

Storage  Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light and moisture. Dispense in a tight, light-resistant closed container.

Incompatibilities:  No data available.

Section 8.  Exposure controls / personal protection

Respiratory Protection  Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection  Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection  Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing  Protective clothing is not normally necessary, however it is good practice to use apron.

Engineering Control  Engineering controls should be used as the primary means to control exposures.
General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Section 9. Physical and chemical properties**

**Appearance**
Zolmitriptan Orally Disintegrating Tablets, 2.5 mg are white/mottled white to cream white, round, flat-faced, uncoated tablet, debossed with ‘715’ on one side and plain on the other side.

Zolmitriptan Orally Disintegrating Tablets, 5 mg are white/mottled white to cream white, round, biconvex, beveled, uncoated tablet, debossed with ‘717’ on one side and plain on the other side.

**Solubility in water**
Readily soluble in Water

**Boiling point**
No Data Available

**Evaporation rate**
No Data Available

**Reactivity in water**
No Data Available

**% Volatile by volume**
No Data Available

**Solubility in water**
Readily soluble in Water

**Odour**
Odourless

**Boiling point**
No Data Available

**Melting Point**
135°C – 141°C

**Evaporation rate**
No Data Available

**Vapour density**
No Data Available

**Reactivity in water**
No Data Available

**Evaporation rate**
No Data Available

**Specific gravity**
No Data Available

**% Volatile by volume**
No Data Available

**Vapour pressure**
No Data Available

**Other information**
Not applicable

**Section 10. Stability and Reactivity**

**Condition to avoid**
Avoid exposure to extreme heat, light and moisture.

**Stable**
Product is stable

**Decomposition Products**
No Data Available

**Hazardous Reaction**
No data available.

**Incompatibilities**
No Data available.

**Section 11. Toxicological information**

**General**
Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

**Target organ**
Eye contact, Skin contact and inhalation is not great risk as this product is Tablets.

**Other**
Not applicable
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Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 202890

Section 16. Other Information

None

Date of issue: 28/05/2015

Supersedes edition of: 01

The information contained herein is based on the state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.