SAFETY DATA SHEET

Zolmitriptan Tablets, USP 2.5 mg and 5 mg

EMERGENCY OVERVIEW

ZOLMITRIPTAN TABLETS, USP contain an active drug substance zolmitriptan and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral tablets.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	Zolmitriptan Tablets, USP
Potencies	**:**	2.5 mg and 5 mg
Chemical Name	**:**	(S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone
Therapeutic Category	**:**	Selective 5-hydroxytryptamine$_{1B/1D}$ (5-HT$_{1B/1D}$) receptor agonist
Product Use	**:**	Acute treatment of migraine with or without aura in adults.
Marketed by	**:**	**Ajanta Pharma USA Inc.** Bridgewater, NJ 08807. Made in India.
Contact Information	**:**	855-664-7744

Section 2. Health hazards information

Potential Health Effects **:**

Inhalation: Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause respiratory irritation.

Eye Contact: Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause eye irritation.

Skin Contact: Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause skin irritation.

Ingestion: Health injuries are not known or expected under normal use.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical form.

Section 3. Composition / information on ingredients

Components Active ingredient	Exposure Limit	CAS No.
Zolmitriptan TWA: Time-Weighted Average	TWA-0.01 mg/m^3	139264-17-8

Inactive ingredients: Each film coated tablets contains the following inactive ingredients include lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol, ferric oxide yellow (2.5 mg and 5 mg tablet), ferric oxide red (2.5 mg tablet).

Section 4. First aid measures

This product in the final dosage form (tablets) does not pose a problem of exposure to active moieties, and does not cause inhalation, skin and eye irritation problem. The lose powder exposure hazards are during the manufacturing process.

Inhalation : If breathing is difficult, remove to fresh air and keep at rest in a position comf011abie for breathing. Call a physician if symptoms develop or persist.

Skin Contact : Rinse skin with water. Get medical attention if irritation develops and persists.

Eye Contact : If the powder enters the eyes, wash victim's eyes under gently running water. Use sufficient force to keep eyelids open, have victim "roll" eyes and flush for at least 15 minutes. Get medical attention if irritation develop and persists.

Ingestion : If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

Medical Treatment : Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control infoll11ation center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within

acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

Overdosage	:	In clinical study subjects who received single 50 mg oral doses of zolmitriptan tablets commonly experienced sedation. There is no specific antidote to zolmitriptan tablets. 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. The elimination half-life of zolmitriptan tablets is 3 hours [see Clinical Pharmacology (12.1)]; therefore, monitor patients after overdose with zolmitriptan tablets for at least 15 hours or until symptoms or signs resolve. It is unknown what effect hemodialysis or peritoneal dialysis has on the plasma concentrations of zolmitriptan.

Section 5. Fire-fighting measures

Flash Point	:	Not available.
Extinguishing Media	:	Water spray, foam, dry chemical or CO_2. Water spray should be used to cool containers.
Special Fire Fighting Procedures	:	For single units (packages): No special requirements needed. Use water spray or fog; do not use straight streams. Dike fire-control water for later disposal; do not scatter the material. Containers may explode when heated. Move containers from fire area if you can do it without risk.
General Fire Hazards/ Hazardous Combustible Products	:	The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate and if it is dispersed. Combustion will evolve toxic vapors.

Section 6. Accidental release measures

Personal Precautions	:	For consumer use, no unusual precautions are necessary. In laboratory, medical or industrial setting wear protective clothing and equipment such as shoe covering, hood and head coverings may be necessary.
Environmental Protections	:	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.

Clean-up Methods	**:**	Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water.

Section 7. Handling and storage

Handling	**:**	No special precautions are necessary when handling packed product. The handling of unpackaged product may require precautions. In case of accident, avoid breathing dust from crushed tablets. Avoid contact with skin and eyes. Follow procedures specified in the National Fire Protection Association Codes and Standards for handling combustible dusts. (or explosive dusts)
Storage	**:**	Store zolmitriptan tablets at 20-25°C (68-77°F) [see USP Controlled Room Temperature]. Protect from light and moisture.

Section 8. Exposure controls/personal protection

Exposure Limits	**:**	TWA-0.01 mg/m^3
Engineering Controls	**:**	For consumer use, no unusual precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation.
Respiratory Protection	**:**	For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting use NIOSH/MSHA approved respirators for protection, if necessary.
Personal Protection	**:**	For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting use of goggles, lab coat and gloves are recommended.
Recommended Facilities	**:**	Eye wash, washing facilities
General hygiene considerations	**:**	Handle in accordance with good hygiene and safety practice.

Section 9. Physical and chemical properties

Appearance	**:**	**Zolmitriptan Tablets, USP 2.5 mg** is Pink, round, biconvex, film-coated tablets with "ZL 1" engraved on one side and break line on other side are supplied as 6 tablets blister pack in a cartons (NDC 27241-021-68).

Zolmitriptan Tablets, USP 5 mg is yellow, round, biconvex, film-coated tablets with "ZL 2" engraved on one side and plain on other side are supplied as 3 tablets blister pack in a cartons (NDC 27241-022-38).

Other Information : **Zolmitriptan drug substance** is white to off white color powder. Zolmitriptan is sparingly soluble in methanol and acetone. Its pKa was established 8.9.

Section 10. Stability and reactivity

Stability : Stable under normal conditions.

Incompatibility materials : None known. The following information refers to active ingredient Zolmitriptan incompatible materials: formaldehyde, alkalis.

Hazardous Decomposition : Zolmitriptan decomposes to carbon monoxide, carbon dioxide, and nitrogen oxides.

Conditions to Avoid : Heat sensitive.

Section 11. Toxicological information

Inhalation : Adverse effects similar to ingestion may occur following exposure to the dust.

Skin Contact : No information available.

Eye Contact : Practically non-irritant to rabbit eyes causing practically no initial pain. Formulation unlikely to cause eye irritation in man.

Ingestion : Harmful if swallowed. Oral Median Lethal Dose (rat) 1,000-1,500 mg/kg. Therapeutic doses may produce chest tightness, pain or pressure, sedation and an increase in blood pressure. May cause nausea, dizziness, dry mouth and taste disturbances.

Long Term Exposure : Studies in animals have shown that high doses produce adverse effects on the thyroid gland, Some evidence of genotoxicity but unlikely to present a carcinogenic hazard to man, Studies in animals have shown that exposures produce no teratogenic effects.

Section 12. Ecological information

Eco toxicity of drug substance: The drug substance in tablet dosage form is not expected to present significant adverse environmental effects.
In the finished product form: There is no potential for air borne contamination since the drug substance is consolidated and contended as film coated tablet dosage form.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods
IMDG: Not available.

Section 15. Regulatory information

DEA: Not available
FDA: Zolmitriptan is an approved prescription medication.
Inventory Status: Not available.

Section 16. Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: Mar 16, 2022

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