SAFETY DATA SHEET

Almotriptan Tablets, USP 6.25 mg and 12.5 mg

EMERGENCY OVERVIEW

ALMOTRIPTAN TABLETS USP contain an active drug substance Almotriptan malate, USP 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	**:**	Almotriptan Tablets, USP
Potencies	**:**	6.25 mg and 12.5 mg
Chemical Name	**:**	1-[[[3-[2-(Dimethylamino) ethyl]-1*H*-indol-5-yl] methyl] sulfonyl] pyrrolidine. Malate
Therapeutic Category	**:**	$5HT_{1B/1D}$ agonist (For treatment of migraine)
Product Use	**:**	Acute treatment of migraine attacks in adults with a history of migraine with or without aura.
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: The product as presented do not pose any inhalation hazard. The active material in the tablets may cause irritation on inhalation.

Eye Contact: The product as presented do not pose any ocular hazard. The active material in the tablets may cause irritation on eye contact.

Skin Contact: The product as presented do not pose any hazard on skin contact. The active material in the tablets may cause irritation on skin contact.

Ingestion: The product as presented do not pose any hazard on ingestion. The active material in the tablets may cause irritation on ingestion.

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

Section 3. Composition / information on ingredients

Components	Exposure Limit	CAS No.
Active ingredient		
Almotriptan Malate	TWA-44 µg/m^3	181183-52-8

TWA: Time-Weighted Average

Inactive ingredients: Each film-coated tablet contains the following inactive ingredients: mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, sodium stearyl fumarate, polyethylene glycol, titanium dioxide and hypromellose.

Section 4. First aid measures

Inhalation : Should not pose a hazard in the final form. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable 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 : Rinse with water. Get medical attention.

Ingestion : If conscious, give water to drink and do not induce vomiting. 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 information 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.

Over dosage : Treatment should be symptomatic and supportive.
Gastrointestinal decontamination by gastric lavage followed by charcoal should be considered. Clinical and electrocardiographic monitoring should be continued at least 20 hours.

Section 5. Fire-fighting measures

Flash Point : Not available.

Extinguishing Media : Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Special Fire Fighting Procedures	:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
General Fire Hazards/ Hazardous Combustible Products	:	The drug substance in the formulation is assumed to be combustible.

Section 6. Accidental release measures

Personal Precautions	:	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Protections	:	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
Clean-up Methods	:	Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7. Handling and storage

Handling	:	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	:	Store at 25°C (77°F); excursions permitted from 15° to 30°C (59° to 86°P) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits	:	TWA- 44 µg/m^3
Engineering Controls	:	Not required when handling tablets or containers. Ventilation should be matched to conditions.
Respiratory Protection	:	Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are necessary. Ventilation should be matched to conditions.
Personal Protection	:	Not required when handling tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves
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 : **Almotriptan Tablets, USP 6.25 mg** White, circular, biconvex, film-coated tablets debossed with 'A1' on one side and plain on other side.
Carton of 6 tablets. Single blister of 6 tablets in each carton. (NDC 27241-041-11)
Blister of 6 tablets (NDC 27241-041-68)

Almotriptan Tablets, USP 12.5 mg White circular, biconvex, film-coated tablets debossed with 'A2' on one side and plain on other side. Carton of 12 tablets. Two blisters of 6 tablets in each carton. (NDC 27241-042-21)
Blister of 6 tablets (NDC 27241-042-68)

Other Information : pKa value of Almotriptan malate is 8.77 at ± 2°C.

Section 10. Stability and reactivity

Stability : Stable
Incompatibility : None known
Hazardous Decomposition : Decomposition product for drug substance are carbon monoxide, carbon dioxide, oxides of nitrogen and oxides of sulphur.
Conditions to Avoid : None known.

Section 11. Toxicological information

Acute toxicity : None known. Minimum lethal dose: 2000 mg/kg (oral, rat).

Carcinogenesis : The carcinogenic potential of almotriptan was evaluated by oral gavage for up to 103 weeks in mice at doses up to 250 mg/kg/day and in rats for up to 104 weeks at doses up to 75 mg/kg/day. Because of high mortality rates in both studies, which reached statistical significance in high dose female mice, all female rats, all male mice, and high dose female mice were terminated between weeks 96 and 98. There was no increase in tumors related to almotriptan administration.

Mutagenesis : Almotriptan was not mutagenic, with or without metabolic activation, in two in vitro gene mutation assays, the Ames test, and the thymidine locus mouse lymphoma assay. Almotriptan was not clastogenic in an in vivo mouse micronucleus assay. Almotriptan produced an equivocal weakly positive response in in vitro cytogenetics assays in human lymphocytes.

Impairment of Fertility : When almotrip1an was administered by oral gavage to pregnant rats throughout the period of organogenesis at doses of 125, 250, 500, and 1000 mg/kg/day, an increase in embryo lethality was seen at the highest dose. Increased incidences of fetal skeletal variations (decreased ossification) were noted at doses greater than 125 mg/kg/day.
Similar studies in rabbits conducted with almotriptan at doses of 5, 20, and 60 mg/kg/day demonstrated increases in embryo lethality at the high dose. When almotriptan was administered to rats throughout the periods of gestation and lactation at doses of 25, 100 and 400 mg/kg/day, gestation length was increased and litter size and offspring body weight were decreased at the high dose. The decrease in pup weight persisted throughout lactation. The no-observed-effect level in this study was 100 mg/kg/day.

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 product is in 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 available
IATA: Not available

Section 15. Regulatory information

DEA: Not available
FDA: Almotriptan 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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