SAFETY DATA SHEET

Lamotrigine Orally Disintegrating Tablets 25 mg, 50 mg, 100 mg and 200 mg

EMERGENCY OVERVIEW

Lamotrigine Orally Disintegrating Tablets contain an active drug substance lamotrigine 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 route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	Lamotrigine Orally Disintegrating Tablets
Potencies	**:**	25 mg, 50 mg, 100 mg and 200 mg
Chemical Name	**:**	6-(2,3-Dichlorophenyl)-1,2,4-triazine-3,5-diamine.
Therapeutic Category	**:**	Anti-epileptic / Anticonvulsant.
Product Use	**:**	Treatment of partial seizures and Lennox-Gastault Syndrome, and for maintenance treatment of Bipolar I Disorder.
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.

Eye Contact: Not expected to be hazardous in final pharmaceutical form.

Skin Contact: May cause an allergic skin reaction.

Ingestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.

Fertility: May damage fertility or the unborn child.

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

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Lamotrigine	8 HR TWA - 200 mcg/m^3 and OHC 2	84057-84-1

Inactive ingredients: The inactive ingredients include artificial peppermint flavor, croscarmellose sodium, microcrystalline cellulose, magnesium stearate, mannitol, colloidal silicon dioxide, pregelatinized starch and sucralose.
Composition of peppermint flavor: Maize maltodextrin, modified corn starch and flavorings.

Section 4. First aid measures

The product in the final dosage form (tablet) does not pose a problem of exposure to active drug substance and should not cause inhalation, skin and eye irritation problem. However, in case of exposure:

Eye Contact : Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin Contact : Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.
Get medical attention if symptoms occur.

Ingestion : If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Inhalation : Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Medical Treatment : No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

Section 5. Fire-fighting measures

Flash Point : Not available.

Extinguishing Media : Extinguish fire with extinguishing agent suitable for the surrounding fire

General Fire Hazards/ Hazardous Combustible Products	:	Water, Foam, Dry chemical powder and Carbon dioxide (CO_2)
Special Fire Fighting Procedures	:	Wear self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode and full protective gear to prevent contact with skin and eyes. Move containers from fire area if you can do so without risk.

Section 6. Accidental release measures

Personal Precautions	:	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep upwind. Keep out of low areas. Wear appropriate protective equipment (see Section 8) and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
Environmental Precautions	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Avoid discharge into drains, water courses or onto the ground.
Clean-up Methods	:	Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water sources, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.
Additional Consideration for Large Spills	:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Move containers from spill area. Clean up operations should only be undertaken by trained personnel.

Section 7. Handling and storage

Handling	:	Avoid breaking or crushing tablets. Avoid prolonged exposure. Observe good industrial hygiene practices. Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. If during normal use the material presents a respiratory hazard, use adequate ventilation or

wear appropriate respirator. Empty product containers and any residue as they can be hazardous. Do not reuse container.

Storage : Recommended storage for Lamotrigine orally disintegrating tablets: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits : 8 HR TWA - 200 mcg/m^3 and OHC - 2

Engineering Controls : In laboratory, medical or industrial setting use appropriate ventilation. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Respiratory Protection : No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Personal Protection : Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Recommended Facilities : None

Section 9. Physical and chemical properties

Appearance : 25 mg, white to off-white, round, flat-faced tablets debossed with “L1” on one side and plain on the other supplied in bottles of 30 with child-resistant closure (NDC 27241-183-30).

50 mg, white to off-white, round, flat-faced tablets debossed with “LT2” on one side and plain on the other supplied in bottles of 30 with child-resistant closure (NDC 27241-184-30).

100 mg, white to off-white, round, flat-faced tablets debossed with “LT3” on one side and plain on the other supplied in bottles of 30 with child-resistant closure (NDC 27241-185-30).

		200 mg, white to off-white, round, flat-faced tablets debossed with “LT5” on one side and plain on the other supplied in bottles of 30 with child-resistant closure (NDC 27241-186-30).
Other Information	**:**	Lamotrigine (Molecular weight: 256.09) is a white to off white powder. It is very slightly soluble in water (approx. 0.17 mg/mL at 25°C) and slightly soluble in 0.1 M HCl (approx.4.1 mg/mL at 25°C).

Section 10. Stability and reactivity

Reactivity	**:**	The product is stable and non-reactive under normal conditions of use, storage and transport.
Stability	**:**	Stable
Incompatibility	**:**	Incompatible with strong oxidizing agents.
Hazardous Decomposition	**:**	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.
Conditions to Avoid	**:**	Incompatible materials and strong oxidants.

Section 11. Toxicological information

Acute toxicity	**:**	Rat Oral LD50: 205 mg/kg
Carcinogenesis	**:**	Carcinogenic effects are not expected because of occupational exposure. Not classifiable as to carcinogenicity to humans.
Mutagenesis	**:**	No data available to indicate product or any components present at greater than 0.1% are mutagenic.
Fertility effects	**:**	No evidence of impaired fertility detected in rats.
Teratogenicity	**:**	No potentially teratogenic effects have been observed in rats.

Section 12. Ecological information

Eco toxicity of drug substance	**:**	In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater.
In the finished product form	**:**	There is no potential for air borne contamination since the drug substance is in consolidated form as tablets.

Section 13. Disposal consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Empty containers or liners may retain some product residues. This material and its container must be disposed in a safe manner. Do not discharge into drains, water courses or onto the ground. The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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 regulated for transport of dangerous goods

Section 15. Regulatory information

DEA: Not classified as control substance.
FDA: Lamotrigine Orally Disintegrating Tablets 25 mg, 50 mg, 100 mg and 200 mg is an approved prescription medication.

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: April 06, 2022

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