SAFETY DATA SHEET

Eletriptan Hydrobromide Tablets
20 mg and 40 mg

EMERGENCY OVERVIEW

Eletriptan Hydrobromide Tablets contain an active drug substance eletriptan hydrobromide 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	:	Eletriptan Hydrobromide Tablets
Potencies	:	20 mg and 40 mg
Chemical Name	:	(R)-3-[(1-Methyl-2-pyrrolidinyl)methyl]-5-[2-phenylsulfonyl)ethyl]-1H-indole monohydrobromide
Therapeutic Category	:	Serotonin (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.

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

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

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.

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		
Eletriptan Hydrobromide	OEL TWA-8 Hr: 0.1 mg/m^3	177834-92-3

Inactive ingredients: Each tablet contains inactive ingredients includes microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, titanium dioxide, hypromellose, triacetin, FD&C Yellow No. 6 aluminum lake.

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.

Eye Contact : Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact : Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion : Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation : Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

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 : The elimination half-life of eletriptan is about 4 hours therefore monitoring of patients after overdose with eletriptan should continue for at least 20 hours or longer while symptoms or signs persist. There is no specific antidote to eletriptan. It is unknown what effect hemodialysis or peritoneal dialysis has on the serum concentration of eletriptan.

Section 5. Fire-fighting measures

Flash Point	:	324.8 °C.
Extinguishing Media	:	Use water spray, foam, dry powder, or carbon dioxide.
General Fire Hazards/ Hazardous Combustible Products	:	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides, and other sulfur- and bromine-containing compounds. Fine particles (such as dust and mists) may fuel fires/explosions.
Special Fire Fighting Procedures	:	For single units (packages): No special requirements needed. For larger amounts (multiple packages) of product: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Section 6. Accidental release measures

Personal Precautions	:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Protections	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	:	Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.
Additional Consideration for Large Spills	:	Vacuum or sweep material into appropriate container for disposal. Avoid generating airborne dust. Close container and move it to a secure holding area. Prevent discharge to drains.

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. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin and clothing. Use adequate ventilation. Minimize dust generation and accumulation.

Storage	:	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits	:	OEL TWA-8 Hr - 0.1 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. However, for handling packets, 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. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended.
Recommended Facilities	:	None

Section 9. Physical and chemical properties

Appearance	:	**Eletriptan Hydrobromide Tablets equivalent to 20 mg base:** Orange, round, biconvex, film-coated tablets, debossed with "E1" on one side and plain on another side. Supplied as single blister of 6 tablets in each carton (NDC 27241-039-11) and blister of 6 tablets (NDC 27241-039-68). **Eletriptan Hydrobromide Tablets equivalent to 40 mg base:** Orange, round, biconvex, film-coated tablets, debossed with "E2" on one side and plain on another side. Supplied as single blister of 6 tablets in each carton (NDC 27241-040-11) and two blisters of 6 tablets in each carton. (NDC 27241-040-21) and blister of 6 tablets (NDC 27241-040-68)
Other Information	:	The molecular formula is $C_{22}H_{26}N_2O_2S$. HBr, representing a molecular weight of 463.43. Eletriptan hydrobromide is a cream to pale brown powder that is readily soluble in water.

Section 10. Stability and reactivity

Stability	:	Stable
Incompatibility	:	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition	:	None expected under normal conditions.
Conditions to Avoid	:	Fine particles (such as dust and mists) may fuel fires/explosions.

Section 11. Toxicological information

Acute toxicity	:	Eletriptan Hydrobromide - Toxicity Data: Oral LDmin. (Rat/Mouse) < 1000 (hemisulfate) mg/kg.
Carcinogenesis	:	None of the components of this product are suspected to be a carcinogen.
Mutagenesis	:	When processed and used as directed, this product is not expected to produce mutagenic effects in humans.
Impairment of Fertility	:	Eletriptan Hydrobromide had no effect on the fertility of male or female rats and is not teratogenic in rats or rabbits.

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. Harmful effects to sensitive species of aquatic organisms could occur. Releases to the environment should be avoided.
In the finished product form	:	There is no potential for air borne contamination since the drug substance is in consolidated form as compressed tablet.

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: If pharmacy service available, return unused capsules to pharmacy for disposal. 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 regulated for transport of dangerous goods

Section 15. Regulatory information

DEA: Not Available.
FDA: Eletriptan Hydrobromide Tablets 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 07, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION