Annora

SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	Eletriptan Hydrobromide Tablets 20 mg & 40 mg Acute treatment of migraine with or without aura in adults
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854

Section 2: Hazard(s) Identification	
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	
Ingredients	**CAS**
Eletriptan Hydrobromide	177834-92-3
Croscarmellose Sodium	74811-65-7
Lactose Monohydrate	64044-51-5
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6
Opadry II orange	NA

Section 4: First-Aid Measures	
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

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	
Physical Form	Tablet
Description	Eletriptan hydrobromide tablets containing 20 mg or 40 mg eletriptan (base) as the hydrobromide salt are supplied as follows: 20 mg - Orange colored, round shaped, bevel edged biconvex film-coated tablets debossed with 'E' on one side 'V' on other side. Carton of 6 tablets (Blister of 6 tablets) NDC 31722-443-31 40 mg - Orange colored, round shaped, bevel edged biconvex film-coated tablets debossed with 'E' on one side 'V1' on other side. Carton of 6 tablets (one Blister of 6 tablets in each carton) NDC 31722-444-31 Carton of 12 tablets (Two Blisters of 6 tablets in each carton) NDC 31722-444-33 Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

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 Considerations

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: Other Information

Issue Date: 29-08-2025

Version: 00

Further information

Revision date: NA

Revision notes: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.