Annora

SAFETY DATA SHEET

Section 1: Identification	
Material	Bupropion Hydrochloride Extended-release Tablets USP, 150 mg and 300 mg
Recommended use	Pharmaceutical product
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Dose and Administration	
General Dosing Considerations	It is particularly important to administer bupropion hydrochloride extended release tablets (XL) in a manner most likely to minimize the risk of seizure. Gradual escalation in dosage is also important if agitation, motor restlessness, and insomnia, often seen during the initial days of treatment, are to be minimized.
Initial Treatment	The usual adult target dose for bupropion hydrochloride extended-release tablets (XL) is 300 mg/day, given once daily in the morning. Dosing with bupropion hydrochloride extended-release tablets (XL) should begin at 150 mg/day given as a single daily dose in the morning. If the 150-mg initial dose is adequately tolerated, an increase to the 300-mg/day target dose, given as once daily, may be made as early as day 4 of dosing. There should be an interval of at least 24 hours between successive doses.
Increasing the Dosage Above 300 mg/day	As with other antidepressants, the full antidepressant effect of bupropion hydrochloride extended-release tablets (XL) may not be evident until 4 weeks of treatment or longer. An increase in dosage to the maximum of 450 mg/day, given as a single dose, may be considered for patients in whom no clinical improvement is noted after several weeks of treatment at 300 mg/day.
Maintenance Treatment	It is generally agreed that acute episodes of depression require several months or longer of sustained pharmacological therapy beyond response to the acute episode. It is unknown whether or not the dose of bupropion hydrochloride

	extended-release tablets (XL) needed for maintenance treatment is identical to the dose needed to achieve an initial response. Patients should be periodically reassessed to determine the need for maintenance treatment and the appropriate dose for such treatment.

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Bupropion Hydrochloride	31677-93-7
Microcrystalline cellulose	9004-34-6
Povidone	9003-39-8
Diluted Hydrochloric acid	7647-01-0
Glyceryl behenate	77538-19-3
Sodium Stearyl fumarate	4070-80-8
Ethyl Cellulose	9004-57-3
Polyethylene glycol	25322-68-3
Isopropyl alcohol	67-63-0
Methylene chloride	75-09-2
Methacrylic Acid and Ethyl Acrylate copolymer Dispersion	25212-88-8
Triethyl citrate	77-93-0
Silicon dioxide	7631-86-9
Opadry Blue	NA
Opadry Orange	NA
Opacode Black	NA

Section 4: First-Aid Measures	
Inhalation	Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
Skin Contact	Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
Eye Contact	Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Overdose Treatment	Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. EEG monitoring is also recommended for the first 48hours post-ingestion. General supportive and symptomatic measures are also recommended. Activated charcoal should be administered. There is no experience with the use of forced diuresis, dialysis, hemoperfusion, or exchange transfusion in the management of bupropion overdoses. Due to the dose-related risk of seizures with bupropion hydrochloride extended release tablets (XL), hospitalization following suspected overdose should be considered. Based on studies in animals, it is recommended that seizures be treated with intravenous benzodiazepine administration supportive
Section 5: Fire-Fighting Measures	
Extinguishing media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.
Fire and Explosion Hazard	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.
Section 6: Accidental Release Measures	
Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site
Section 7: Handling and Storage	
Storage	Store at 20º to 25ºC (68º to 77ºF); excursions permitted to 15º to 30ºC (59º to 86ºF) [see USP Controlled Room Temperature].
Section 8: Exposure controls / personal protection	
Respiratory protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary; however, it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary; however, it is good practice to use apron.
Section 9: Physical and Chemical Properties	
Physical State	Extended Release Tablet
Description	150 mg: Blue colored, round bevel edged, biconvex film-coated tablets imprinted with "V1 71" on one side and plain on other side. They are supplied as: Bottle of 30 tablets NDC 31722-487-30 Bottle of 90 tablets NDC 31722-487-90 Bottle of 500 tablets NDC 31722-487-05 300 mg: Peach colored, round bevel edged biconvex film-coated tablets, imprinted with "V1 72" on one side and plain on other side. They are supplied as: Bottle of 30 tablets NDC 31722-488-30 Bottle of 90 tablets NDC 31722-488-90 Bottle of 500 tablets NDC 31722-488-05
Section 10: Stability and Reactivity	
Condition to avoid	Avoid exposure to extreme heat, light and moisture.
Stable	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available
Hazardous Reaction	No Data Available
Incompatibilities	No Data Available

Section 11: Toxicological Information	
General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet
Other	Not Applicable

Section 12: Ecological Information
Do not allow product to enter drinking water supplies, waste water or soil

Section 13 Disposal Considerations	
Disposal:	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14: Transport Information
The product is not hazards when shipped via air (IATA), ground (DOT), or sea (IMDG).

Section 15: Regulatory Information
Generic Medicine. Approved by USFDA & the ANDA

Section 16: Other Information, including date of preparation or last revision
Issue Date: 14-04-2026 **Version: 00** **Further information** **Revision date: Nil** **Revision note: Nil.** 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.