

Safety Data Sheet
Bupropion Hydrochloride Extended-release Tablets (XL)

Strength: 300 mg. **Pack Size:** 30/500/1000 Tablets per bottle

Revision No.: 02

EMERGENCY OVERVIEW

Each Bupropion Hydrochloride Extended-release Tablet contain Bupropion hydrochloride and excipients generally considered to be non -toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

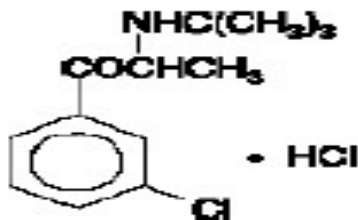
Section 1. Identification

Identification of the product

Product name: Bupropion Hydrochloride Extended-release Tablets (XL)

Formula: $C_{13}H_{18}ClNO \cdot HCl$.

Chemical Name: (\pm)-1-(3-chlorophenyl)-2-[(1,1-dimethylethyl)amino]-1-propanone hydrochloride.



Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India

Address: Sarkhej – Bavla N.H. 8A, Moraiya. Tal. Sanand.
Dist. Ahmedabad – 382210. State: Gujarat. India

Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319

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**Recommended use /
Therapeutic Category** Antidepressant

**Restriction on Use /
Contraindications:** Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients with a seizure disorder.

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Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients with a current or prior diagnosis of bulimia or anorexia nervosa because of a higher incidence of seizures noted in patients treated for bulimia with the immediate-release formulation of bupropion.

Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines).

Section 2. Hazard(s) Information

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. If necessary, these effects may be managed by temporary reduction of dose or the short-term administration of an intermediate to long-acting sedative hypnotic. A sedative hypnotic usually is not required beyond the first week of treatment. Insomnia may also be minimized by avoiding bedtime doses. If distressing, untoward effects supervene, dose escalation should be stopped. bupropion hydrochloride extended-release tablets (XL) should be swallowed whole and not crushed, divided, or chewed, as this may lead to an increased risk of adverse effects including seizures. Bupropion hydrochloride extended-release tablets (XL) may be taken without regard to meals.

Major Depressive Disorder

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.

Seasonal Affective Disorder

For the prevention of seasonal major depressive episodes associated with seasonal affective disorder, bupropion hydrochloride extended-release tablets (XL) should generally be initiated in the autumn prior to the onset of depressive symptoms. Treatment should continue through the winter season and should be tapered and discontinued in early spring. The timing of initiation and duration of treatment should be individualized based on the patient's historical pattern of seasonal major depressive episodes. Patients whose seasonal depressive episodes are infrequent or not associated with significant impairment should not generally be treated prophylactically.

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, the dose of bupropion hydrochloride extended-release tablets (XL) should be increased to the 300-mg/day dose after 1 week. If the 300-mg dose is not adequately tolerated, the dose can be reduced to 150 mg/day. The usual adult target dose for bupropion hydrochloride extended-release tablets (XL) is 300 mg/day, given once daily in the morning.

For patients taking 300 mg/day during the autumn-winter season, the dose should be tapered to 150 mg/day for 2 weeks prior to discontinuation.

Doses of bupropion hydrochloride extended-release tablets (XL) above 300 mg/day have not been studied for the prevention of seasonal major depressive episodes.

Switching Patients from bupropion hydrochloride tablets or from bupropion hydrochloride sustained-release tablets:

When switching patients from bupropion hydrochloride tablets to bupropion hydrochloride extended-release tablets (XL) or from bupropion hydrochloride sustained-Release Tablets to bupropion hydrochloride extended-release tablets (XL), give the same total daily dose when possible. Patients who are currently being treated with bupropion hydrochloride tablets at 300 mg/day (for example, 100 mg 3 times a day) may be switched to bupropion hydrochloride extended-release tablets (XL) 300 mg once daily. Patients who are currently being treated with bupropion hydrochloride sustained-release tablets at 300 mg/day (for example, 150 mg twice daily) may be switched to bupropion hydrochloride extended-release tablets (XL) 300 mg once daily.

Dosage Adjustment for Patients With Impaired Hepatic Function

Bupropion hydrochloride extended-release tablets (XL) should be used with extreme caution in patients with severe hepatic cirrhosis. The dose should not exceed 150 mg every other day in these patients. Bupropion hydrochloride extended-release tablets (XL) should be used with caution in patients with hepatic impairment (including mild to moderate hepatic cirrhosis) and a reduced frequency and/or dose should be considered in patients with mild to moderate hepatic cirrhosis .

Dosage Adjustment for Patients With Impaired Renal Function

Bupropion hydrochloride extended-release tablets (XL) should be used with caution in patients with renal impairment and a reduced frequency and/or dose should be considered .

Adverse Effects

Bupropion hydrochloride extended-release tablets (XL) can cause serious side effects. Read this entire Medication Guide for more information about these serious side effects.

Common side effects reported in studies of major depressive disorder include weight loss, loss of appetite, dry mouth, skin rash, sweating, ringing in the ears, shakiness, stomach pain, agitation, anxiety, dizziness, trouble sleeping, muscle pain, nausea, fast heartbeat, sore throat, and urinating more often. In studies of seasonal affective disorder, common side effects included weight loss, constipation, and gas.

If you have nausea, take your medicine with food. If you have trouble sleeping, do not take your medicine too close to bedtime.

These are not all the side effects of bupropion hydrochloride extended-release tablets (XL). For a complete list, ask your doctor or pharmacist.

Over Dose Effect

Overdoses of up to 30 g or more of bupropion have been reported. Seizure was reported in approximately one third of all cases. Other serious reactions reported with overdoses of bupropion alone included hallucinations, loss of consciousness, sinus tachycardia, and ECG changes such as conduction disturbances (including QRS prolongation) or arrhythmias. Fever, muscle rigidity, rhabdomyolysis, hypotension, stupor, coma, and respiratory failure have been reported mainly when bupropion was part of multiple drug overdoses.

Although most patients recovered without sequelae, deaths associated with overdoses of bupropion alone have been reported in patients ingesting large doses of the drug. Multiple uncontrolled seizures, bradycardia, cardiac failure, and cardiac arrest prior to death were reported in these patients.

Medical Conditions

Tell your doctor if you have ever had depression, suicidal thoughts or actions, or other mental health problems. See “Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal Thoughts or Actions.”

Tell your doctor about your other medical conditions including if you:

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- are pregnant or plan to become pregnant. It is not known if bupropion hydrochloride extended-release tablets (XL) can harm your unborn baby.
 - are breastfeeding. bupropion hydrochloride extended-release tablets (XL) pass through your milk. It is not known if bupropion hydrochloride extended-release tablets (XL) can harm your baby.
 - have liver problems, especially cirrhosis of the liver.
 - have kidney problems.
 - have an eating disorder such as anorexia nervosa or bulimia.
 - have had a head injury.
 - have had a seizure (convulsion, fit).
 - have a tumor in your nervous system (brain or spine).
 - have had a heart attack, heart problems, or high blood pressure.
 - are a diabetic taking insulin or other medicines to control your blood sugar.
 - drink a lot of alcohol.
 - abuse prescription medicines or street drugs.
 - Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Many medicines increase your chances of having seizures or other serious side effects if you take them while you are using bupropion hydrochloride extended-release tablets (XL).

Contraindications

Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients with a seizure disorder.

Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients treated with ZYBAN[®] (bupropion hydrochloride) sustained-release tablets; bupropion hydrochloride tablets, the immediate-release formulation; bupropion hydrochloride sustained-release tablets, the sustained-release formulation; or any other medications that contain bupropion because the incidence of seizure is dose dependent.

Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients with a current or prior diagnosis of bulimia or anorexia nervosa because of a higher incidence of seizures noted in patients treated for bulimia with the immediate-release formulation of bupropion.

Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines).

The concurrent administration of bupropion hydrochloride extended-release tablets (XL) and a monoamine oxidase (MAO) inhibitor is contraindicated. At least 14 days should elapse between discontinuation of an MAO inhibitor and initiation of treatment with bupropion hydrochloride extended-release tablets (XL).

Bupropion hydrochloride extended-release tablet (XL) is contraindicated in patients who have shown an allergic response to **bupropion or the** other ingredients that make up bupropion hydrochloride extended-release tablets (XL).

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Pregnancy Comments Bupropion hydrochloride extended-release tablets (XL) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Bupropion hydrochloride.	Not Found	31677-93-7
Inactive ingredients :		
Hypromellose	Not Found	9004-65-3
Magnesium stearate	Not Found	577-04-0
Ethylcellulose	Not Found	9004-57-3
Polyethylene glycol	Not Found	25322-68-3
Triethyl citrate.	Not Found	77-93-0
Silicon dioxide	Not Found	7631-86-9
Povidone	Not Found	9003-39-8
Methacrylic acid copolymer dispersion	Not Found	NA

Section 4. First -aid measures

General

Inhalation: Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

contact with skin: Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

contact with eyes: Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Ingestion: If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice

Remove and wash/dispose of contaminated clothing promptly.

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Overdose Treatment Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. EEG monitoring is also recommended for the first 48 hours post-ingestion. General supportive and symptomatic measures are also recommended. Induction of emesis is not 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. No specific antidotes for bupropion are known.

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 and other supportive measures, as appropriate.

In managing over dosage, consider the possibility of multiple drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of any overdose. Telephone numbers for certified poison control centers are listed in the *Physicians' Desk Reference* (PDR).

Section 5. Fire -fighting measures

Flash point	Not Found	Upper Flammable Limit:	Not Found
Auto-Ignition Temperature:	Not Found	Lower Flammable Limit:	Not Found
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.		

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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 20° to 25°C (68° to 77°F).
Dispense in a tight container.

Incompatibilities No data available.

Section 8. Exposure controls and 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

Appearance Bupropion hydrochloride extended-release tablets (XL), 300 mg are creamy-white to pale-yellow, round, biconvex, coated-tablets imprinted with '354' in black ink on one side and plain on other side .

Solubility	Highly soluble in water, in 0.1 N hydrochloric acid, and in alcohol.	Odour	Produces the sensation of local anesthesia on the oral mucosa.
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Boiling point	No Data Available	Melting Point	No Data Available
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Evaporation rate	No Data Available	Vapour density	No Data Available
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Reactivity in water	No Data Available	Evaporation rate	No Data Available
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Percentage Volatile by volume	No Data Available	Specific gravity	No Data Available
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Vapour pressure	No Data Available	Other information	Not Applicable
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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.
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Decomposition Products	No Data Available	Hazardous Reaction	No data available.
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Incompatibilities	No data available.
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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.
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Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
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Other	Not Applicable
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Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Disposal:	Dispose the waste in accordance with all applicable Federal, State and local laws.
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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 Number is 201567

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Section 16. Other information

None

Date of issue: 28/05/2015

Supersedes edition of: 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.