Bupro-D™

Dextromethorphan Hydrobromide BP
and Bupropion Hydrochloride USP

Composition:
Bupro-D™: Each extended release tablet contains Dextromethorphan Hydrobromide BP 45 mg and Bupropion Hydrochloride USP 105 mg.

Pharmacology:
Bupro-D™ is a combined preparation of Dextromethorphan Hydrobromide and Bupropion Hydrochloride. Dextromethorphan is an uncompetitive antagonist of the NMDA receptor (an ionotropic glutamate receptor) and a sigma-1 receptor agonist. The mechanism of Dextromethorphan in the treatment of MDD is unclear. The mechanism of action of bupropion in the treatment of MDD is unclear; however, it may be related to Noradrenergic and/or Dopaminergic mechanisms. Bupropion increases plasma levels of Dextromethorphan by competitively inhibiting cytochrome P450 2D6, which catalyzes a major biotransformation pathway for Dextromethorphan. Bupropion is a relatively weak inhibitor of the neuronal reuptake of Norepinephrine and Dopamine and does not inhibit monoamine oxidase or the reuptake of Serotonin.

Indications:
Major depressive disorder (MDD) in adults.

Dosage & Administration:
Starting dosage is one tablet once daily in the morning. After 3 days, increase to the maximum recommended dosage of one tablet twice daily, separated by at least 8 hours. Do not exceed two doses within the same day.

Overdose
dextromethorphan overdose include nausea, vomiting, stupor, coma, respiratory depression, seizures, tachycardia, hyperexcitability, and toxic psychosis. Bupropion overdoses can causes hallucinations, loss of consciousness, mental status changes, sinus tachycardia, QRS prolongation, arrhythmias, clonus, myoclonus, and hyperreflexia, fever, muscle rigidity, rhabdomyolysis, hypotension, coma, and respiratory failure.

Contraindications
- Seizure disorder
- Current or prior diagnosis of bulimia or anorexia nervosa
- Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- Do not use within 14 days of discontinuing an MAOI
- Known hypersensitivity to Bupropion or Dextromethorphan

Warnings & Precautions
- Seizure: Risk is dose-related. Discontinue if seizure occurs.
- Increased Blood Pressure and Hypertension: **Bupro-D™** can increase blood pressure and cause hypertension. Need to assess blood pressure before initiating treatment and monitor periodically during treatment.
- Activation of Mania or Hypomania: Screen patients for bipolar disorder.
- Serotonin Syndrome: Use with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants increases the risk.

Avoid use in case of severe renal or hepatic impairment.

Side effects
Dizziness, headache, somnolence, diarrhoea, dry mouth, sexual dysfunction and hyperhidrosis.

Use in Pregnancy and Lactation
Pregnancy: Not recommended during pregnancy as the combination may cause fetal harm if administered during pregnancy.
Lactation: Not recommended during treatment and for 5 days following final dose.

Use in children & adolescents
The safety and effectiveness of **Bupro-D™** have not been established. Antidepressants, including bupropion, increase the risk of suicidal thoughts and behaviors in pediatric patients.

Drug Interactions
- Strong CYP2D6 inhibitors: Recommended dosage is one tablet by mouth once daily in the morning.
- Strong CYP2B6 inducers: Avoid use.
- CYP2D6 Substrates: Increases the exposures of drugs that are substrates of CYP2D6.
- Digoxin: May decrease plasma digoxin levels. Monitor digoxin levels.
- Drugs that lower seizure threshold: Coadministration may increase risk of seizure.
- Dopaminergic drugs: Central Nervous System (CNS) toxicity can occur with concomitant use.

Storage
Store below 25°C temperature. Protect from light and moisture. Keep out of reach of children.

How Supplied
Bupro-D™: Each box contains 30 Tablets in Alu-Alu blister pack.

Manufactured by -
SQUARE
PHARMACEUTICALS PLC.
Kaliakoir, Gazipur, Bangladesh