

DEXBUTRIN

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for DEXBUTRIN (Dextromethorphan Hydrobromide & Bupropion Hydrochloride Extended Release Tablets 45 mg+ 105 mg)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: 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.

INDICATION: It is indicated for the Treatment of major depressive disorder (MDD) in adults.

DOSAGE AND ADMINISTRATION: The recommended starting dosage of DEXBUTRIN (45 mg of dextromethorphan hydrobromide and 105 mg of bupropion hydrochloride) is one tablet once daily in the morning. After 3 days, increase to the maximum recommended dosage of one tablet twice daily, given at least 8 hours apart. Do not exceed two doses within the same day.

CONTRAINDICATION: DEXBUTRIN is contraindicated in patients with a seizure disorder, with a current or prior diagnosis of bulimia or anorexia nervosa as a higher incidence of seizures was observed in such patients treated with the immediate-release formulation of bupropion, undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs, taking, or within 14 days of stopping, MAOIs due to the risk of serious and possibly fatal drug interactions, including hypertensive crisis and serotonin syndrome, with known hypersensitivity to bupropion, dextromethorphan, or other components of Dexbutrin. Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported with bupropion. Arthralgia, myalgia, fever with rash, and other serum sickness-like symptoms suggestive of delayed hypersensitivity have also been reported with bupropion.

WARNINGS & PRECAUTIONS: Suicidal Thoughts and Behaviors in Adolescents and Young Adults Seizure, Increased Blood Pressure and Hypertension, Activation of Mania or Hypomania, Psychosis and Other Neuropsychiatric Reactions, Angle-Closure Glaucoma, Dizziness, Serotonin Syndrome, Embryo-fetal Toxicity.

DRUG INTERACTION: It can interact with Monoamine Oxidase Inhibitors (MAOIs), Serotonergic Drugs, Drugs that Lower Seizure Threshold, Strong Inhibitors of CYP2D6, Strong Inducers of CYP2B6, Drugs Metabolized by CYP2D6, Digoxin, Dopaminergic Drugs, Alcohol, Drug-Laboratory Test Interactions.

ADVERSE REACTIONS: •The adverse reactions are suicidal thoughts and behaviors in adolescents and young adults, seizure, increased blood pressure and hypertension, activation of mania or hypomania, psychosis and other neuropsychiatric reactions, angle-closure glaucoma, dizziness, serotonin syndrome, embryo-fetal toxicity.

MARKETED BY:



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(Additional information is available on request)