

ONCE-DAILY BUPROPION HCl EXTENDED-RELEASE TABLETS, USP (XL)



To most, “generics” means bland, ordinary, and uninteresting. To us, it means the opportunity to be remarkable.

See reverse side for important safety information.

— MAKING —
GENERIC
REMARKABLE

PRODUCT DETAILS

- Strength: Available in 150 mg and 300 mg tablets
- Therapeutic Class: Antidepressant

NDC Numbers:

150 mg | Bottle of 30: **70436-010-04**
150 mg | Bottle of 90: **70436-010-06**
150 mg | Bottle of 500: **70436-010-02**
300 mg | Bottle of 30: **70436-011-04**
300 mg | Bottle of 90: **70436-011-06**
300 mg | Bottle of 500: **70436-011-02**

To place an order or learn more, call **844-529-8988 (Toll Free)** or email sales@slaterunpharma.com

6am – 7pm CST (Monday - Friday)

Available through your wholesaler:

NDC: 70436-010-04

Cardinal Health: 5541354
McKesson: 3974359
Amerisource: 10230252

NDC: 70436-010-06

Cardinal Health: 5541362
McKesson: 3974367
Amerisource: 10229689

NDC: 70436-010-02

Cardinal Health: 5526991
McKesson: 3974375
Amerisource: 10229773

NDC: 70436-011-04

Cardinal Health: 5536701
McKesson: 3974391
Amerisource: 10229737

NDC: 70436-011-06

Cardinal Health: 5541370
McKesson: 3676115
Amerisource: 10229772

NDC: 70436-011-02

Cardinal Health: 5527007
McKesson: 3974409
Amerisource: 10229738

IMPORTANT SAFETY INFORMATION FOR:

BUPROPION HYDROCHLORIDE EXTENDED-RELEASE TABLETS (XL)

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. These trials did not show an increase in the risk of suicidal thought and behavior with antidepressant use in subjects aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

Bupropion hydrochloride extended-release tablets (XL) are contraindicated in:

- Patients with seizure disorder.
- Patients with a current or prior diagnosis of bulimia or anorexia nervosa
- Patients undergoing discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs.
- The use of Monoamine Oxidase Inhibitors (MAOIs) (intended to treat psychiatric disorders) concomitantly with bupropion hydrochloride extended-release tablets (XL) or within 14 days of discontinuing treatment with bupropion hydrochloride extended-release tablets (XL) is contraindicated. The use of bupropion hydrochloride extended-release tablets (XL) within 14 days of discontinuing treatment with an MAOI is also contraindicated.
- Patients with known hypersensitivity to bupropion or other ingredients in bupropion hydrochloride extended-release tablets (XL). Anaphylactoid/anaphylactic reaction and Stevens-Johnson Syndrome has been reported.

Bupropion hydrochloride extended-release tablets (XL) are not approved for smoking cessation treatment; however, bupropion HCL sustained release is approved for this use. Serious neuropsychiatric adverse events have been reported in patients taking bupropion for smoking cessation including changes in mood (including depression and mania), psychosis, hallucination, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide.

Bupropion hydrochloride extended-release tablets (XL) can cause seizure. The risk of seizures is dose-related. The dose should not exceed 300 mg once daily. The dose should be increased gradually and bupropion hydrochloride extended-release tablets (XL) should be discontinued if a patient experiences a seizure.

Treatment with bupropion hydrochloride extended-release tablets (XL) can result in elevated blood pressure. Blood pressure should be evaluated at initial time of treatment and periodically during treatment. Adverse events that occurred in at least 5% of patients treated with bupropion HCL sustained-release (300 mg and 400 mg per day) and at a rate of at least twice the placebo rate include: anorexia, dry mouth, rash, sweating, tinnitus, tremor, abdominal pain, agitation, anxiety, dizziness, insomnia, myalgia, nausea, palpitation, pharyngitis, and urinary frequency.

Please see the package insert for Bupropion Hydrochloride Extended Release Tablets (XL) for full prescribing information.