

BUPROPION HCI

EXTENDED-RELEASE TABLETS USP (SR)



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

See reverse side for important safety information.



PRODUCT DETAILS

- Strength: Available in 100 mg, 150 mg, and 200 mg tablets
- · Therapeutic Class: Antidepressant

NDC Numbers:

100 mg | Bottle of 100: **70436-058-01** 100 mg | Bottle of 500: **70436-058-02** 150 mg | Bottle of 100: **70436-059-01** 150 mg | Bottle of 250: **70436-059-22** 150 mg | Bottle of 500: **70436-059-02** 200 mg | Bottle of 100: **70436-060-01**

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: 70436-058-01

Cardinal Health: 5673413 McKesson: 1570027 Amerisource: 10249744

NDC: 70436-058-02

Cardinal Health: 5673421 McKesson: 1570035 Amerisource: 10249713

NDC: 70436-059-01

Cardinal Health: 5673439 McKesson: 1570043 Amerisource: 10249742

NDC: 70436-059-22

Cardinal Health: 5687926 McKesson: 1584648 Amerisource: 10252107

NDC: 70436-059-02

Cardinal Health: 5673447 McKesson: 1570050 Amerisource: 10249743

NDC: 70436-060-01

Cardinal Health: 5673454 McKesson: 1570068 Amerisource: 10249745 IMPORTANT SAFETY INFORMATION FOR:

BUPROPION HYDROCHLORIDE EXTENDED-RELEASE TABLETS (SR)

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 thoughts and behavior with antidepressant use in subjects over age 24; there was reduction in risk 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 (SR) 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 (SR) or within 14 days of discontinuing treatment with Bupropion Hydrochloride Extended-Release Tablets (SR) is contraindicated. The use of Bupropion Hydrochloride Extended-Release Tablets (SR) within 14 days of discontinuing treatment with an MAOI is also contraindicated. Starting Bupropion Hydrochloride Extended-Release Tablets (SR) in a patient treated with reversible MAOIs such as linezolid or methylene blue is contraindicated.
- Patients with known hypersensitivity to bupropion or other ingredients in Bupropion Hydrochloride Extended-Release Tablets (SR). Anaphylactoid/anaphylactic reaction and Stevens-Johnson syndrome has been reported.

Bupropion Hydrochloride Extended-Release Tablets (SR) are not approved for smoking cessation treatment; however, it contains the same active ingredient as the smoking cessation medication ZYBAN. 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 (SR) can cause seizure. The risk of seizures is dose-related. The dose should not exceed 400 mg/day. The dose should be increased gradually and Bupropion Hydrochloride Extended-Release Tablets (SR) should be discontinued if a patient experiences a seizure.

Treatment with Bupropion Hydrochloride Extended-Release Tablets (SR) can result in elevated blood pressure. Blood pressure should be evaluated at initial time of treatment and periodically during treatment.

The most common adverse reactions (incidence $\geq 5\%$ and $\geq 2\%$ more than placebo rate) are: headache, dry mouth, nausea, insomnia, dizziness, pharyngitis, constipation, agitation, anxiety, abdominal pain, tinnitus, tremor, palpitation, myalgia, sweating, rash, and anorexia.

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