**BUPROPION HYDROCHLORIDE SR- bupropion hydrochloride sr tablet, film coated, extended release**
**DirectRx**

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## BUPROPION HCL ER (SR)

Bupropion hydrochloride extended-release tablets (SR) is indicated for the treatment of major depressive disorder (MDD), as defined by the Diagnostic and Statistical Manual (DSM).

The efficacy of bupropion in the treatment of a major depressive episode was established in two 4-week controlled inpatient trials and one 6-week controlled outpatient trial of adult subjects with MDD [see Clinical Studies ( 14)] .

The efficacy of bupropion hydrochloride extended-release tablets (SR) in maintaining an antidepressant response for up to 44 weeks following 8 weeks of acute treatment was demonstrated in a placebo-controlled trial [see Clinical Studies ( 14)] .

2.1 General Instructions for Use
To minimize the risk of seizure, increase the dose gradually [see Warnings and Precautions ( 5.3)] . Bupropion hydrochloride extended-release tablets (SR) should be swallowed whole and not crushed, divided, or chewed. Bupropion hydrochloride extended-release tablets (SR) may be taken with or without food.

The usual adult target dose for bupropion hydrochloride extended-release tablets (SR) is 300 mg/day, given as 150 mg twice daily. Initiate dosing with 150 mg/day given as a single daily dose in the morning. After 3 days of dosing, the dose may be increased to the 300-mg/day target dose, given as 150 mg twice daily. There should be an interval of at least 8 hours between successive doses. A maximum of 400 mg/day, given as 200 mg twice daily, may be considered for patients in whom no clinical improvement is noted after several weeks of treatment at 300 mg/day. To avoid high peak concentrations of bupropion and/or its metabolites, do not exceed 200 mg in any single dose.

It is generally agreed that acute episodes of depression require several months or longer of antidepressant drug treatment beyond the response in the acute episode. It is unknown whether the dose of bupropion hydrochloride extended-release tablets (SR) needed for maintenance treatment is identical to the dose that provided an initial response. Periodically reassess the need for maintenance treatment and the appropriate dose for such treatment.

2.2 Dose Adjustment in Patients with Hepatic Impairment
In patients with moderate to severe hepatic impairment (Child-Pugh score: 7 to 15), the maximum dose of bupropion hydrochloride extended-release tablets (SR) is 100 mg/day or 150 mg every other day. In patients with mild hepatic impairment (Child-Pugh score: 5 to 6), consider reducing the dose and/or frequency of dosing [see Use in Specific Populations ( 8.7), Clinical Pharmacology ( 12.3)].

2.3 Dose Adjustment in Patients with Renal Impairment
Consider reducing the dose and/or frequency of bupropion hydrochloride extended-release tablets (SR) in patients with renal impairment (Glomerular Filtration Rate less than 90 mL/min) [see Use in Specific Populations ( 8.6), Clinical Pharmacology ( 12.3)] .

2.4 Switching a Patient to or from a Monoamine Oxidase Inhibitor (MAOI) Antidepressant

At least 14 days should elapse between discontinuation of an MAOI intended to treat depression and initiation of therapy with bupropion hydrochloride extended-release tablets (SR). Conversely, at least 14 days should be allowed after stopping bupropion hydrochloride extended-release tablets (SR) before starting an MAOI antidepressant [see Contraindications ( 4), Drug Interactions ( 7.6)] .

2.5 Use of Bupropion Hydrochloride Extended-Release Tablets (SR) with Reversible MAOIs Such as Linezolid or Methylene Blue

Do not start bupropion hydrochloride extended-release tablets (SR) in a patient who is being treated with a reversible MAOI such as linezolid or intravenous methylene blue. Drug interactions can increase the risk of hypertensive reactions. In a patient who requires more urgent treatment of a psychiatric condition, non-pharmacological interventions, including hospitalization, should be considered [see Contraindications ( 4), Drug Interactions ( 7.6)] .

In some cases, a patient already receiving therapy with bupropion hydrochloride extended-release tablets (SR) may require urgent treatment with linezolid or intravenous methylene blue. If acceptable alternatives to linezolid or intravenous methylene blue treatment are not available and the potential benefits of linezolid or intravenous methylene blue treatment are judged to outweigh the risks of hypertensive reactions in a particular patient, bupropion hydrochloride extended-release tablets (SR) should be stopped promptly, and linezolid or intravenous methylene blue can be administered. The patient should be monitored for 2 weeks or until 24 hours after the last dose of linezolid or intravenous methylene blue, whichever comes first. Therapy with bupropion hydrochloride extended-release tablets (SR) may be resumed 24 hours after the last dose of linezolid or intravenous methylene blue.

The risk of administering methylene blue by non-intravenous routes (such as oral tablets or by local injection) or in intravenous doses much lower than 1 mg/kg with bupropion hydrochloride extended-release tablets (SR) is unclear. The clinician should, nevertheless, be aware of the possibility of a drug interaction with such use [see Contraindications ( 4), Drug Interactions ( 7.6)] .

100 mg – blue, round, biconvex, film coated tablets, debossed with ‘SG, 174’ on one side and plain on other side.

150 mg – purple, round, biconvex, film coated tablets, debossed with ‘SG, 175’ on one side and plain on other side.

200 mg – pink, round, biconvex, film coated tablets, debossed with ‘SG, 176’ on one side and plain on other side.

Bupropion hydrochloride extended-release tablets (SR) are contraindicated in patients with a seizure disorder.

Bupropion hydrochloride extended-release tablets (SR) are contraindicated in patients 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 [see Warnings and Precautions ( 5.3)].

Bupropion hydrochloride extended-release tablets (SR) are contraindicated in patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs [see Warnings and Precautions ( 5.3), Drug Interactions ( 7.3)] .

The use of 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. There is an increased risk of hypertensive reactions when bupropion hydrochloride extended-release tablets (SR) are used concomitantly with MAOIs. 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 intravenous methylene blue is contraindicated [see Dosage and Administration ( 2.4, 2.5), Warnings and Precautions ( 5.4), Drug Interactions ( 7.6)].
Bupropion hydrochloride extended-release tablets (SR) are contraindicated in patients with known hypersensitivity to bupropion or other ingredients of bupropion hydrochloride extended-release tablets (SR). Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported [see Warnings and Precautions ( 5.8)].

5.1 Suicidal Thoughts and Behaviors in Children, Adolescents, and Young Adults
Patients with MDD, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (selective serotonin reuptake inhibitors [SSRIs] and others) show that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18 to 24) with MDD and other psychiatric disorders. Short-term clinical trials did not show an increase in the risk of suicidality with antidepressants compared with placebo in adults beyond age 24; there was a reduction with antidepressants compared with placebo in adults aged 65 and older.
The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short term trials of 9 antidepressant drugs in over 4,400 subjects. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 subjects. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger subjects for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs. placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1,000 subjects treated) are provided in TABLE 1.
Table 1. Risk Differences in the Number of Suicidality Cases by Age Group in the Pooled Placebo-Controlled Trials of Antidepressants in Pediatric and Adult Subjects

| Age Range | Drug-Placebo Difference in Number of Cases of Suicidality per 1,000 Subjects Treated |
|---|---|
| Increases Compared With Placebo | |
| <18 | 14 additional cases |
| 18 to 24 | 5 additional cases |
| Decreases Compared With Placebo | |

25 to 64
1 fewer case
≥65
6 fewer cases
No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide.
It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression.
All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases [see BOXED WARNING] .
The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.
Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.
Families and caregivers of patients being treated with antidepressants for MDD or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for bupropion hydrochloride extended-release tablets (SR) should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.
5.2 Neuropsychiatric Adverse Events and Suicide Risk in Smoking Cessation Treatment
Bupropion hydrochloride extended-release tablets (SR) is 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. These postmarketing reports have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide [see Adverse Reactions ( 6.2)] . Some patients who stopped smoking may have been experiencing symptoms of nicotine withdrawal, including depressed mood. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these adverse events occurred in patients taking bupropion who continued to smoke.
Neuropsychiatric adverse events occurred in patients without and with pre-existing

psychiatric disease; some patients experienced worsening of their psychiatric illnesses. Observe patients for the occurrence of neuropsychiatric adverse events. Advise patients and caregivers that the patient should stop taking bupropion hydrochloride extended-release tablets and contact a healthcare provider immediately if agitation, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior. In many postmarketing cases, resolution of symptoms after discontinuation of bupropion was reported. However, the symptoms persisted in some cases; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.

5.3 Seizure

Bupropion hydrochloride extended-release tablets (SR) can cause seizure. The risk of seizure is dose-related. The dose should not exceed 400 mg per day. Increase the dose gradually. Discontinue bupropion hydrochloride extended-release tablets (SR) and do not restart treatment if the patient experiences a seizure.

The risk of seizures is also related to patient factors, clinical situations, and concomitant medications that lower the seizure threshold. Consider these risks before initiating treatment with bupropion hydrochloride extended-release tablets (SR). Bupropion hydrochloride extended-release tablets (SR) are contraindicated in patients with a seizure disorder, current or prior diagnosis of anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs [see Contraindications ( 4), Drug Interactions ( 7.3)] . The following conditions can also increase the risk of seizure: severe head injury; arteriovenous malformation; CNS tumor or CNS infection; severe stroke; concomitant use of other medications that lower the seizure threshold (e.g., other bupropion products, antipsychotics, tricyclic antidepressants, theophylline, and systemic corticosteroids); metabolic disorders (e.g., hypoglycemia, hyponatremia, severe hepatic impairment, and hypoxia); use of illicit drugs (e.g., cocaine); or abuse or misuse of prescription drugs such as CNS stimulants. Additional predisposing conditions include diabetes mellitus treated with oral hypoglycemic drugs or insulin; use of anorectic drugs; and excessive use of alcohol, benzodiazepines, sedative/hypnotics, or opiates.

Incidence of Seizure with Bupropion Use:

When bupropion hydrochloride extended-release tablets (SR) are dosed up to 300 mg per day, the incidence of seizure is approximately 0.1% (1/1,000) and increases to approximately 0.4% (4/1,000) at the maximum recommended dose of 400 mg/day. The risk of seizure can be reduced if the dose of bupropion hydrochloride extended-release tablets (SR) does not exceed 400 mg/day, given as 200 mg twice daily, and the titration rate is gradual.

5.4 Hypertension

Treatment with bupropion hydrochloride extended-release tablets (SR) can result in elevated blood pressure and hypertension. Assess blood pressure before initiating treatment with bupropion hydrochloride extended-release tablets (SR), and monitor periodically during treatment. The risk of hypertension is increased if bupropion hydrochloride extended-release tablets (SR) are used concomitantly with MAOIs or other drugs that increase dopaminergic or noradrenergic activity [see Contraindications ( 4)].

Data from a comparative trial of the sustained-release formulation of bupropion HCl, nicotine transdermal system (NTS), the combination of sustained-release bupropion plus NTS, and placebo as an aid to smoking cessation suggest a higher incidence of treatment-emergent hypertension in patients treated with the combination of sustained-release bupropion and NTS. In this trial, 6.1% of subjects treated with the combination of sustained-release bupropion and NTS had treatment-emergent hypertension compared

with 2.5%, 1.6%, and 3.1% of subjects treated with sustained-release bupropion, NTS, and placebo, respectively. The majority of these subjects had evidence of pre-existing hypertension. Three subjects (1.2%) treated with the combination of sustained-release bupropion and NTS and 1 subject (0.4%) treated with NTS had study medication discontinued due to hypertension compared with none of the subjects treated with sustained-release bupropion or placebo. Monitoring of blood pressure is recommended in patients who receive the combination of bupropion and nicotine replacement.
In a clinical trial of bupropion immediate-release in MDD subjects with stable congestive heart failure (N = 36), bupropion was associated with an exacerbation of pre-existing hypertension in 2 subjects, leading to discontinuation of bupropion treatment. There are no controlled trials assessing the safety of bupropion in patients with a recent history of myocardial infarction or unstable cardiac disease.

5.5 Activation of Mania/Hypomania

Antidepressant treatment can precipitate a manic, mixed, or hypomanic manic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating bupropion hydrochloride extended-release tablets (SR), screen patients for a history of bipolar disorder and the presence of risk factors for bipolar disorder (e.g., family history of bipolar disorder, suicide, or depression). Bupropion hydrochloride extended-release tablets (SR) are not approved for use in treating bipolar depression.

5.6 Psychosis and Other Neuropsychiatric Reactions

Depressed patients treated with bupropion hydrochloride extended-release tablets (SR) have had a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. Some of these patients had a diagnosis of bipolar disorder. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment. Instruct patients to contact a healthcare professional if such reactions occur.

5.7 Angle-Closure Glaucoma

The pupillary dilation that occurs following use of many antidepressant drugs including bupropion hydrochloride extended-release tablets (SR) may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.

5.8 Hypersensitivity Reactions

Anaphylactoid/anaphylactic reactions have occurred during clinical trials with bupropion. Reactions have been characterized by pruritus, urticaria, angioedema, and dyspnea requiring medical treatment. In addition, there have been rare, spontaneous postmarketing reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock associated with bupropion. Instruct patients to discontinue bupropion hydrochloride extended-release tablets (SR) and consult a healthcare provider if they develop an allergic or anaphylactoid/anaphylactic reaction (e.g., skin rash, pruritus, hives, chest pain, edema, and shortness of breath) during treatment. There are reports of arthralgia, myalgia, fever with rash, and other serum sickness-like symptoms suggestive of delayed hypersensitivity.

The following adverse reactions are discussed in greater detail in other sections of the labeling:
Suicidal thoughts and behaviors in adolescents and young adults [see BOXED WARNING, Warnings and Precautions ( 5.1)]
Neuropsychiatric symptoms and suicide risk in smoking cessation treatment [see Warnings and Precautions ( 5.2)]

Seizure [see Warnings and Precautions ( 5.3)]
Hypertension [see Warnings and Precautions ( 5.4)]
Activation of mania or hypomania [see Warnings and Precautions ( 5.5)]
Psychosis and other neuropsychiatric reactions [see Warnings and Precautions ( 5.6)]
Angle-closure glaucoma [see Warnings and Precautions ( 5.7)]
Hypersensitivity reactions [see Warnings and Precautions ( 5.8)]

## 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

### Adverse Reactions Leading to Discontinuation of Treatment

In placebo-controlled clinical trials, 4%, 9%, and 11% of the placebo, 300 mg/day, and 400 mg/day groups, respectively, discontinued treatment due to adverse reactions. The specific adverse reactions leading to discontinuation in at least 1% of the 300 mg/day or 400 mg/day groups and at a rate at least twice the placebo rate are listed in Table 2.

Table 2. Treatment Discontinuations Due to Adverse Reactions in Placebo-Controlled Trials

| Adverse Reaction | Placebo (n = 385) | Bupropion Hydrochloride Extended-release Tablets (SR) 300 mg/day (n = 376) | Bupropion Hydrochloride Extended-release Tablets (SR) 400 mg/day (n = 114) |
|---|---|---|---|
| Rash | 0.0% | 2.4% | 0.9% |
| Nausea | 0.3% | 0.8% | 1.8% |
| Agitation | 0.3% | 0.3% | 1.8% |
| Migraine | 0.3% | 0.0% | 1.8% |

### Commonly Observed Adverse Reactions

Adverse reactions from Table 3 occurring in at least 5% of subjects treated with bupropion hydrochloride extended-release tablets (SR) and at a rate at least twice the placebo rate are listed below for the 300 mg/day and 400 mg/day dose groups.

Bupropion hydrochloride extended-release tablets (SR) 300 mg/day: Anorexia, dry mouth, rash, sweating, tinnitus, and tremor.

Bupropion hydrochloride extended-release tablets (SR) 400 mg/day: Abdominal pain, agitation, anxiety, dizziness, dry mouth, insomnia, myalgia, nausea, palpitation, pharyngitis, sweating, tinnitus, and urinary frequency.

Adverse reactions reported in placebo-controlled trials are presented in TABLE 3. Reported adverse reactions were classified using a COSTART-based Dictionary.

Table 3. Adverse Reactions Reported by at Least 1% of Subjects and at a Greater Frequency than Placebo in Controlled Clinical Trials

| Body System/ Adverse Reaction | Bupropion Hydrochloride Extended-release Tablets (SR) 300 mg/day (n = 376) | Bupropion Hydrochloride Extended-release Tablets (SR) 400 mg/day (n = 114) | Placebo (n = 385) |
|---|---|---|---|
| Body (General) | | | |
| Headache | 26% | 25% | 23% |
| Infection | 8% | 9% | 6% |
| Abdominal pain | 3% | 9% | 2% |
| Asthenia | 2% | 4% | 2% |
| Chest pain | 3% | 4% | 1% |
| Pain | 2% | 3% | 2% |
| Fever | 1% | 2% | — |
| Cardiovascular | | | |
| Palpitation | 2% | 6% | 2% |
| Flushing | 1% | 4% | — |
| Migraine | 1% | 4% | 1% |
| Hot flashes | 1% | 3% | 1% |
| Digestive | | | |
| Dry mouth | 17% | 24% | 7% |
| Nausea | 13% | 18% | 8% |
| Constipation | 10% | 5% | 7% |
| Diarrhea | 5% | 7% | 6% |
| Anorexia | 5% | 3% | 2% |
| Vomiting | 4% | 2% | 2% |
| Dysphagia | 0% | 2% | 0% |
| Musculoskeletal | | | |
| Myalgia | 2% | 6% | 3% |
| Arthralgia | 1% | 4% | 1% |
| Arthritis | 0% | 2% | 0% |
| Twitch | 1% | 2% | — |
| Nervous system | | | |
| Insomnia | 11% | 16% | 6% |
| Dizziness | 7% | 11% | 5% |
| Agitation | 3% | 9% | 2% |
| Anxiety | 5% | 6% | 3% |
| Tremor | 6% | 3% | 1% |
| Nervousness | 5% | 3% | 3% |
| Somnolence | 2% | 3% | 2% |
| Irritability | 3% | 2% | 2% |
| Memory decreased | — | 3% | 1% |
| Paresthesia | 1% | 2% | 1% |
| Central nervous system stimulation | 2% | 1% | 1% |

Respiratory
Pharyngitis 3% 11% 2%
Sinusitis 3% 1% 2%
Increased cough 1% 2% 1%
Skin
Sweating 6% 5% 2%
Rash 5% 4% 1%
Pruritus 2% 4% 2%
Urticaria 2% 1% 0%
Special senses
Tinnitus 6% 6% 2%
Taste perversion 2% 4% —
Blurred vision or diplopia 3% 2% 2%
Urogenital
Urinary frequency 2% 5% 2%
Urinary urgency — 2% 0%
Vaginal hemorrhage a 0% 2% —
Urinary tract infection 1% 0% —
aIncidence based on the number of female subjects.
— Hyphen denotes adverse events occurring in greater than 0 but less than 0.5% of subjects.
Other Adverse Reactions Observed During the Clinical Development of Bupropion
In addition to the adverse reactions noted above, the following adverse reactions have been reported in clinical trials with the sustained-release formulation of bupropion in depressed subjects and in nondepressed smokers, as well as in clinical trials with the immediate release formulation of bupropion.
Adverse reaction frequencies represent the proportion of subjects who experienced a treatment-emergent adverse reaction on at least one occasion in placebo-controlled trials for depression (n = 987) or smoking cessation (n = 1,013), or subjects who experienced an adverse reaction requiring discontinuation of treatment in an open-label surveillance trial with bupropion hydrochloride extended-release tablets (SR) (n = 3,100). All treatment-emergent adverse reactions are included except those listed in Table 3, those listed in other safety-related sections of the prescribing information, those subsumed under COSTART terms that are either overly general or excessively specific so as to be uninformative, those not reasonably associated with the use of the drug, and those that were not serious and occurred in fewer than 2 subjects.
Adverse reactions are further categorized by body system and listed in order of decreasing frequency according to the following definitions of frequency: Frequent adverse reactions are defined as those occurring in at least 1/100 subjects. Infrequent adverse reactions are those occurring in 1/100 to 1/1,000 subjects, while rare events are those occurring in less than 1/1,000 subjects.
Body (General): Infrequent were chills, facial edema, and photosensitivity. Rare was malaise.
Cardiovascular: Infrequent were postural hypotension, stroke, tachycardia, and vasodilation. Rare were syncope and myocardial infarction.
Digestive: Infrequent were abnormal liver function, bruxism, gastric reflux, gingivitis, increased salivation, jaundice, mouth ulcers, stomatitis, and thirst. Rare was edema of tongue.
Hemic and Lymphatic: Infrequent was ecchymosis.
Metabolic and Nutritional: Infrequent were edema and peripheral edema.

Musculoskeletal: Infrequent were leg cramps.
Nervous System: Infrequent were abnormal coordination, decreased libido, depersonalization, dysphoria, emotional lability, hostility, hyperkinesia, hypertonia, hypesthesia, suicidal ideation, and vertigo. Rare were amnesia, ataxia, derealization, and hypomania.
Respiratory: Rare was bronchospasm.
Special Senses: Infrequent were accommodation abnormality and dry eye.
Urogenital: Infrequent were impotence, polyuria, and prostate disorder.
Changes in Body Weight
In placebo-controlled trials, subjects experienced weight gain or weight loss as shown in TABLE 4.
Table 4. Incidence of Weight Gain and Weight Loss (≥5 lbs) in Placebo-Controlled Trials
Weight Change Bupropion Hydrochloride Extended-release Tablets (SR) 300 mg/day (n = 339)
Bupropion Hydrochloride Extended-release Tablets (SR) 400 mg/day (n = 112)
Placebo (n = 347)
Gained >5 lbs 3% 2% 4%
Lost >5 lbs 14% 19% 6%
In clinical trials conducted with the immediate release formulation of bupropion, 35% of subjects receiving tricyclic antidepressants gained weight, compared with 9% of subjects treated with the immediate-release formulation of bupropion. If weight loss is a major presenting sign of a patient's depressive illness, the anorectic and/or weight reducing potential of bupropion hydrochloride extended-release tablets (SR) should be considered.
6.2 Postmarketing Experience
The following adverse reactions have been identified during post-approval use of bupropion hydrochloride extended-release tablets (SR) and are not described elsewhere in the label. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
Body (General)
Arthralgia, myalgia, and fever with rash and other symptoms suggestive of delayed hypersensitivity. These symptoms may resemble serum sickness [see Warnings and Precautions ( 5.8)].
Cardiovascular
Complete atrioventricular block, extrasystoles, hypotension, hypertension (in some cases severe), phlebitis, and pulmonary embolism.
Digestive
Colitis, esophagitis, gastrointestinal hemorrhage, gum hemorrhage, hepatitis, intestinal perforation, pancreatitis, and stomach ulcer.
Endocrine
Hyperglycemia, hypoglycemia, hyponatremia, and syndrome of inappropriate antidiuretic hormone secretion.
Hemic and Lymphatic
Anemia, leukocytosis, leukopenia, lymphadenopathy, pancytopenia, and thrombocytopenia. Altered PT and/or INR, infrequently associated with hemorrhagic or thrombotic complications, were observed when bupropion was coadministered with warfarin.

Metabolic and Nutritional
Glycosuria.
Musculoskeletal
Muscle rigidity/fever/rhabdomyolysis and muscle weakness.
Nervous System
Abnormal electroencephalogram (EEG), aggression, akinesia, aphasia, coma, completed suicide, delirium, delusions, dysarthria, euphoria, extrapyramidal syndrome (dyskinesia, dystonia, hypokinesia, parkinsonism), hallucinations, increased libido, manic reaction, neuralgia, neuropathy, paranoid ideation, restlessness, suicide attempt, and unmasking tardive dyskinesia.
Respiratory
Pneumonia.
Skin
Alopecia, angioedema, exfoliative dermatitis, hirsutism, and Stevens-Johnson syndrome.
Special Senses
Deafness, increased intraocular pressure, and mydriasis.
Urogenital
Abnormal ejaculation, cystitis, dyspareunia, dysuria, gynecomastia, menopause, painful erection, salpingitis, urinary incontinence, urinary retention, and vaginitis.

10.1 Human Overdose Experience
Overdoses of up to 30 grams 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, mental status changes, sinus tachycardia, ECG changes such as conduction disturbances (including QRS prolongation) or arrhythmias, clonus, myoclonus, and hyperreflexia. 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.

10.2 Overdosage Management
Consult a Certified Poison Control Center for up-to-date guidance and advice. Telephone numbers for certified poison control centers are listed in the Physician’s Desk Reference (PDR). Call 1-800-222-1222 or refer to www.poison.org.

There are no known antidotes for bupropion. In case of an overdose, provide supportive care, including close medical supervision and monitoring. Consider the possibility of multiple drug overdose. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Induction of emesis is not recommended.

Bupropion hydrochloride extended-release tablets, USP (SR), an antidepressant of the aminoketone class, is chemically unrelated to tricyclic, tetracyclic, selective serotonin re-uptake inhibitor, or other known antidepressant agents. Its structure closely resembles that of diethylpropion; it is related to phenylethylamines. It is designated as (±)-1-(3-chlorophenyl)-2-[(1,1dimethylethyl)amino]-1-propanone hydrochloride. The molecular weight is 276.2. The molecular formula is C 13H 18ClNO•HCl. Bupropion hydrochloride powder is white, powder, soluble in 0.1N HCl, alcohol 96% and in water. It has a bitter taste and produces the sensation of local anesthesia on the oral mucosa. The structural

formula is:

Chemical Structure
Bupropion hydrochloride extended-release tablets, USP (SR), are supplied for oral administration as 100 mg (blue), 150 mg (purple), and 200 mg (pink), film-coated, extended-release tablets. Each tablet contains the labeled amount of bupropion hydrochloride and the inactive ingredients: copovidone, cysteine hydrochloride,hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol,polysorbate 80 and titanium dioxide.In addition, the 100 mg tablet contains FD&C Blue No. 1 Brilliant Blue FCF Aluminium Lake, the 150 mg tablet contains FD&C Blue No. 2 Indigo Carmine Aluminium Lake and FD&C Red No. 40 Allura Red AC Aluminium Lake, and the 200 mg tablet contains FD&C Red No. 40 Allura Red AC Aluminium Lake. In addition, flavoring agent contains dextrose, ethyl alcohol, gum arabic, propylene glycol and silicon dioxide.

Bupropion hydrochloride extended-release tablets, USP (SR) meets USP Dissolution Test 2.

MEDICATION GUIDE
Bupropion Hydrochloride Extended-Release Tablets, USP (SR)
(bue proe' pee on hye" droe klor' ide)
IMPORTANT: Be sure to read the three sections of this Medication Guide. The first section is about the risk of suicidal thoughts and actions with antidepressant medicines; the second section is about the risk of changes in thinking and behavior, depression and suicidal thoughts or actions with medicines used to quit smoking; and the third section is entitled “What Other Important Information Should I Know About bupropion hydrochloride extended-release tablets, (SR)?”
Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal Thoughts or Actions
This section of the Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines.
What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions?
Antidepressant medicines may increase the risk of suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment.
Depression or other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have (or have a family history of) bipolar illness (also called manic- depressive illness) or suicidal thoughts or actions.
How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?
Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
Keep all follow-up visits with your healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.
Call your healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

• thoughts about suicide or dying • trouble sleeping (insomnia)
• attempts to commit suicide
• new or worse irritability
• new or worse depression • acting aggressive, being angry, or violent
• new or worse anxiety • acting on dangerous impulses
• feeling very agitated or restless • an extreme increase in activity and talking (mania)
• panic attacks • other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms.

Antidepressants are medicines used to treat depression and other illnesses. It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.

Antidepressant medicines have other side effects. Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.

Antidepressant medicines can interact with other medicines. Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.

It is not known if bupropion hydrochloride extended-release tablets (SR) are safe and effective in children under the age of 18.

Quitting Smoking, Quit-Smoking Medications, Changes in Thinking and Behavior, Depression, and Suicidal Thoughts or Actions

This section of the Medication Guide is only about the risk of changes in thinking and behavior, depression and suicidal thoughts or actions with drugs used to quit smoking.

Although bupropion hydrochloride extended-release tablets, (SR) is not a treatment for quitting smoking, it contains the same active ingredient (bupropion hydrochloride) as ZYBAN which is used to help patients quit smoking.

Talk to your healthcare provider or your family member’s healthcare provider about:
all risks and benefits of quit-smoking medicines
all treatment choices for quitting smoking

When you try to quit smoking, with or without bupropion you may have symptoms that may be due to nicotine withdrawal, including:
• urge to smoke • frustration • restlessness
• depressed mood • anger • decreased heart rate
• trouble sleeping • feeling anxious • increased appetite
• irritability • difficulty concentrating • weight gain

Some people have even experienced suicidal thoughts when trying to quit smoking without medication. Sometimes quitting smoking can lead to worsening of mental health problems that you already have, such as depression.

Some people have had serious side effect while taking bupropion to help them quit smoking, including: New or worse mental health problems, such as changes in behavior or thinking, aggression, hostility, agitation, depression, or suicidal thoughts or actions. Some people had these symptoms when they began taking bupropion, and others developed them after several weeks of treatment, or after stopping bupropion. These symptoms happened more often in people who had a history of mental health problems before taking bupropion than in people without a history of mental health problems.

Stop taking bupropion hydrochloride extended-release tablets, (SR) and call your healthcare provider right away if you, your family, or caregiver notice any of these

symptoms. Work with your healthcare provider to decide whether you should continue to take bupropion hydrochloride extended-release tablets, (SR). In many people, these symptoms went away after stopping bupropion hydrochloride extended-release tablets, (SR), but in some people symptoms continued after stopping bupropion hydrochloride extended-release tablets, (SR). It is important for you to follow-up with your healthcare provider until your symptoms go away. Before taking bupropion hydrochloride extended-release tablets, (SR) tell your healthcare provider if you have ever had depression or other mental health problems. You should also tell your healthcare provider about any symptoms you had during other times you tried to quit smoking, with or without bupropion.

What Other Important Information Should I Know About bupropion hydrochloride extended-release tablets, (SR)?

Seizures: There is a chance of having a seizure (convulsion, fit) with bupropion hydrochloride extended-release tablets, (SR), especially in people:

with certain medical problems.

who take certain medicines.

The chance of having seizures increases with higher doses of bupropion hydrochloride extended-release tablets, (SR). For more information, see the sections “Who should not take bupropion hydrochloride extended-release tablets, (SR)?” and “What should I tell my healthcare provider before taking bupropion hydrochloride extended-release tablets, (SR)?” Tell your healthcare provider about all of your medical conditions and all the medicines you take. Do not take any other medicines while you are taking bupropion hydrochloride tablets, (SR) unless your healthcare provider has said it is okay to take them.

If you have a seizure while taking bupropion hydrochloride extended-release tablets, (SR), stop taking the tablets and call your healthcare provider right away. Do not take bupropion hydrochloride extended-release tablets, (SR) again if you have a seizure.

High blood pressure (hypertension). Some people get high blood pressure, that can be severe, while taking bupropion hydrochloride extended-release tablets, (SR). The chance of high blood pressure may be higher if you also use nicotine replacement therapy (such as a nicotine patch) to help you stop smoking (see the section of this Medication Guide called “How should I take bupropion hydrochloride extended-release tablets, (SR)?”).

Manic episodes. Some people may have periods of mania while taking bupropion hydrochloride extended-release tablets (SR), including:

Greatly increased energy

Severe trouble sleeping

Racing thoughts

Reckless behavior

Unusually grand ideas

Excessive happiness or irritability

Talking more or faster than usual

If you have any of the above symptoms of mania, call your healthcare provider.

Unusual thoughts or behaviors. Some patients have unusual thoughts or behaviors while taking bupropion hydrochloride extended-release tablets, (SR), including delusions (believe you are someone else), hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are against you), or feeling confused. If this happens to you, call your healthcare provider.

Visual problems.

eye pain

changes in vision

swelling or redness in or around the eye
Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
Severe allergic reactions. Some people can have severe allergic reactions to bupropion hydrochloride extended-release tablets (SR). Stop taking bupropion hydrochloride extended-release tablets (SR) and call your healthcare provider right away if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be signs of a serious allergic reaction.
What are bupropion hydrochloride extended-release tablets, (SR)?
Bupropion hydrochloride extended-release tablets, (SR) are a prescription medicine used to treat adults with a certain type of depression called major depressive disorder.
Who should not take bupropion hydrochloride extended-release tablets, (SR)?
Do not take bupropion hydrochloride extended-release tablets, (SR) if you:
have or had a seizure disorder or epilepsy.
have or had an eating disorder such as anorexia nervosa or bulimia.
are taking any other medicines that contain bupropion, including ZYBAN (used to help people stop smoking) WELLBUTRIN ®, WELLBUTRIN XL ®, APLENZIN ®, FORFIVO XL ®. Bupropion is the same active ingredient that is in bupropion hydrochloride extended-release tablets (SR).
drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these make you sleepy), benzodiazepines, or anti-seizure medicines, and you stop using them all of a sudden.
take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
do not take an MAOI within 2 weeks of stopping bupropion hydrochloride extended-release tablets, (SR) unless directed to do so by your healthcare provider.
do not start bupropion hydrochloride extended-release tablets, (SR) if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.
are allergic to the active ingredient in bupropion hydrochloride extended-release tablets, (SR), bupropion, or to any of the inactive ingredients. See the end of this Medication Guide for a complete list of ingredients in bupropion hydrochloride extended-release tablets, (SR).
What should I tell my healthcare provider before taking bupropion hydrochloride extended-release tablets, (SR)?
Tell your healthcare provider 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 healthcare provider about your other medical conditions including if you:
have liver problems, especially cirrhosis of the liver.
have kidney problems.
have, or have had, 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 alcohol.
abuse prescription medicines or street drugs.
are pregnant or plan to become pregnant. Talk to your healthcare provider about the

risk to your unborn baby if you take bupropion hydrochloride extended-release tablets, (SR) during pregnancy.
Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with bupropion hydrochloride extended-release tablets, (SR).
If you become pregnant during treatment with bupropion hydrochloride extended-release tablets, (SR), talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185.
are breastfeeding or plan to breastfeed during treatment with bupropion hydrochloride extended-release tablets, (SR). Bupropion hydrochloride passes into your milk. Talk to your healthcare provider about the best way to feed your baby during treatment with bupropion hydrochloride extended-release tablets, (SR).
Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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 taking bupropion hydrochloride extended-release tablets, (SR).
How should I take bupropion hydrochloride extended-release tablets, (SR)?
Take bupropion hydrochloride extended-release tablets, (SR) exactly as prescribed by your healthcare provider. Do not change your dose or stop taking bupropion hydrochloride extended-release tablets, (SR) without talking to your healthcare provider first.
Swallow bupropion hydrochloride extended-release tablets, (SR) whole. Do not chew, cut, or crush bupropion hydrochloride extended-release tablets, (SR). If you do, the medicine will be released into your body too quickly. If this happens you may be more likely to get side effects including seizures. Tell your healthcare provider if you cannot swallow tablets.
Bupropion hydrochloride extended-release tablets, (SR ) tablets may have an odor. This is normal.
Take bupropion hydrochloride extended-release tablets, (SR) at the same time each day. Take your doses of bupropion hydrochloride extended-release tablets, (SR) at least 8 hours apart.
You may take bupropion hydrochloride extended-release tablets, (SR) with or without food.
If you miss a dose, do not take an extra dose to make up for the dose you missed. Wait and take your next dose at the regular time. This is very important. Too much bupropion hydrochloride extended-release tablets, (SR) can increase your chance of having a seizure.
If you take too much bupropion hydrochloride extended-release tablets, (SR), or overdose, call your local emergency room or poison control center right away.
Do not take any other medicines while taking bupropion hydrochloride extended-release tablets, (SR) unless your healthcare provider has told you it is okay.
If you are taking bupropion hydrochloride extended-release tablets, (SR) for the treatment of major depressive disorder, it may take several weeks for you to feel that bupropion hydrochloride extended-release tablets, (SR) is working. Once you feel better, it is important to keep taking bupropion hydrochloride extended-release tablets, (SR) exactly as directed by your healthcare provider. Call your healthcare provider if you do not feel bupropion hydrochloride extended-release tablets, (SR) is working for you.
What should I avoid while taking bupropion hydrochloride extended-release tablets, (SR)?
Limit or avoid using alcohol during treatment with bupropion hydrochloride extended-release tablets, (SR). If you usually drink a lot of alcohol, talk with your healthcare

provider before suddenly stopping. If you suddenly stop drinking alcohol, you may increase your chance of having seizures.
Do not drive a car or use heavy machinery until you know how bupropion hydrochloride extended-release tablets, (SR) affects you. Bupropion hydrochloride extended-release tablets, (SR) can affect your ability to do these things safely.
What are possible side effects of bupropion hydrochloride extended-release tablets, (SR)?
Bupropion hydrochloride extended-release tablets, (SR) can cause serious side effects. See the sections at the beginning of this Medication Guide for information about serious side effects of bupropion hydrochloride extended-release tablets.
The most common side effects of bupropion hydrochloride extended-release tablets, (SR) include
headache • dizziness
dry mouth • sore throat
nausea • constipation
trouble sleeping
If you have nausea, take your medicine with food. If you have trouble sleeping, do not take your medicine too close to bedtime.
Tell your healthcare provider right away about any side effects that bother you.
These are not all the possible side effects of bupropion hydrochloride extended-release tablets (SR). For more information, ask your healthcare provider or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to ScieGen Pharmaceuticals, Inc. at 1-855-724-3436.
How should I store bupropion hydrochloride extended-release tablets, (SR)?
Store bupropion hydrochloride extended-release tablets, (SR) at room temperature between 20° and 25°C (68° to 77°F).
Keep bupropion hydrochloride extended-release tablets, (SR) dry and out of the light.
Keep bupropion hydrochloride extended-release tablets, (SR) and all medicines out of the reach of children.
General information about bupropion hydrochloride extended-release tablets, (SR).
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use bupropion hydrochloride extended-release tablets, (SR) for a condition for which it was not prescribed. Do not give bupropion hydrochloride extended-release tablets, (SR) to other people, even if they have the same symptoms you have. It may harm them.
If you take a urine drug screening test, bupropion hydrochloride extended-release tablets, (SR) may make the test result positive for amphetamines. If you tell the person giving you the drug screening test that you are taking bupropion hydrochloride extended-release tablets, (SR), they can do a more specific drug screening test that should not have this problem.
This Medication Guide summarizes important information about bupropion hydrochloride extended-release tablets, (SR). If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about bupropion hydrochloride extended-release tablets, (SR) that is written for healthcare professionals.
For more information about bupropion hydrochloride extended-release tablets, (SR), call ScieGen Pharmaceuticals, Inc. at 1-855-724-3436.
What are the ingredients in bupropion hydrochloride extended-release tablets, USP (SR)?

Active ingredient: bupropion hydrochloride USP.
Inactive ingredients: copovidone, cysteine hydrochloride, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80 and titanium dioxide. In addition, the 100 mg tablet contains FD&C Blue No. 1 Brilliant Blue FCF Aluminium Lake, the 150 mg tablet contains FD&C Blue No. 2 Indigo Carmine Aluminium Lake and FD&C Red No. 40 Allura Red AC Aluminium Lake, and the 200 mg tablet contains FD&C Red No. 40 Allura Red AC Aluminium Lake. In addition, flavoring agent contains dextrose, ethyl alcohol, gum arabic, propylene glycol and silicon dioxide.
This Medication Guide has been approved by the U.S. Food and Drug Administration.
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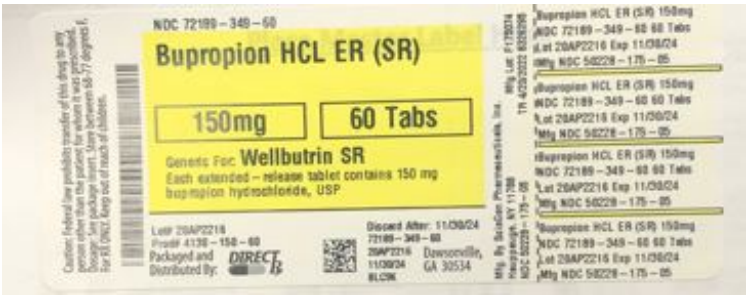
Rx Only
Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788, USA
Rev: 3/2021





## BUPROPION HYDROCHLORIDE SR

bupropion hydrochloride sr tablet, film coated, extended release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:72189-349(NDC:50228-175) |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **BUPROPION HYDROCHLORIDE** (UNII: ZG7E5POY8O) (BUPROPION - UNII:01ZG3TPX31) | BUPROPION HYDROCHLORIDE | 150 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **ACACIA** (UNII: 5C5403N26O) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **DEXTROSE, UNSPECIFIED FORM** (UNII: IY9XDZ35W2) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **COPOVIDONE K25-31** (UNII: D9C330MD8B) | |
| **CYSTEINE HYDROCHLORIDE** (UNII: ZT934N0X4W) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | purple | **Score** | no score |
| **Shape** | ROUND ((biconvex)) | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | SG;175 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:72189-349-60 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 04/22/2022 | |
| **2** | NDC:72189-349-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 08/09/2022 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA205794 | 04/22/2022 | |

## Labeler - DirectRx (079254320)

## Registrant - DirectRx (079254320)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| DirectRx | | 079254320 | repack(72189-349) |

Revised: 7/2023