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Wellbutrin SR (bupropion hydrochloride) - Drug Summary

GlaxoSmithKline LLC

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Wellbutrin SR (bupropion hydrochloride)

BOXED WARNING

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. Monitor closely for worsening, and for emergence of suicidal thoughts and behavior. Advise families and caregivers of the need for close observation and communication w/ the prescriber. Serious neuropsychiatric reactions reported in patients taking bupropion for smoking cessation; not approved for smoking cessation.

View FDA-Approved Full Prescribing Information for Wellbutrin SR

THERAPEUTIC CLASS

Aminoketone

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Major Depressive Disorder

Initial: 150mg/day given as a single daily dose in am
Titrate: After 3 days, may increase dose to 150mg bid w/ an interval of at least 8 hrs between successive doses
Usual Target Dose: 300mg/day, given as 150mg bid
Max: May consider 400mg/day, given as 200mg bid, if no clinical improvement after several weeks of treatment at 300mg/day; do not exceed 200mg in any single dose

Dosing Considerations with MAOIs

Switching to/from an MAOI Antidepressant:
Allow at least 14 days between discontinuation of an MAOI and initiation of treatment and allow at least 14 days between discontinuation of treatment and initiation of an MAOI

Use w/ Reversible MAOIs (eg, Linezolid, IV Methylene Blue):
Do not start bupropion in a patient being treated w/ a reversible MAOI
If acceptable alternatives to linezolid or IV methylene blue treatment are not available and potential benefits of linezolid or IV methylene blue treatment are judged to outweigh risks of hypertensive reactions, bupropion should be stopped promptly, and linezolid or IV methylene blue can be administered
Monitor for 2 weeks or until 24 hrs after the last dose of linezolid or IV methylene blue, whichever comes 1st
May resume bupropion treatment 24 hrs after the last dose of linezolid or IV methylene blue

DOSING CONSIDERATIONS

Renal Impairment
Consider reducing frequency and/or dose

Hepatic Impairment
Mild (Child-Pugh Score: 5-6): Consider reducing frequency and/or dose
Moderate to Severe (Child-Pugh Score: 7-15): Max of 100mg/day or 150mg qod

ADMINISTRATION

Oral route

Take w/ or w/o food
Swallow whole; do not crush, divide, or chew

HOW SUPPLIED

Tab, Sustained-Release: 100mg, 150mg, 200mg

CONTRAINDICATIONS

Seizure disorder, current/prior diagnosis of bulimia or anorexia nervosa. Use of MAOIs (intended to treat psychiatric disorders) either concomitantly or w/in 14 days of discontinuing treatment. Treatment w/in 14 days of discontinuing treatment w/ an MAOI. Starting treatment in patients being treated w/ reversible MAOIs (eg, linezolid, IV methylene blue). Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs.

WARNINGS/PRECAUTIONS

Dose-related risk of seizures; titrate dose gradually. D/C and do not restart treatment if a seizure occurs. May result in elevated BP and HTN. Caution w/ conditions that may increase risk of seizure. May precipitate a manic, mixed, or hypomanic manic episode; not approved for use in treating bipolar depression. Neuropsychiatric signs and symptoms (eg, delusions, hallucinations, psychosis, concentration disturbance) reported. Pupillary dilation that occurs following use may trigger an angle-closure attack in a patient w/ anatomically narrow angles who does not have a patent iridectomy. D/C treatment if allergic or anaphylactoid/anaphylactic reactions occur. Arthralgia, myalgia, fever w/ rash, and other serum sickness-like symptoms suggestive of delayed hypersensitivity reported. False (+) urine immunoassay screening tests for amphetamines reported.

ADVERSE REACTIONS

Abdominal pain, dry mouth, anorexia, insomnia, dizziness, agitation, anxiety, pharyngitis, sweating, rash, tinnitus, tremor, myalgia, nausea, palpitation.

DRUG INTERACTIONS

See Contraindications. Extreme caution w/ other drugs that lower seizure threshold (eg, other bupropion products, antipsychotics, antidepressants, theophylline, systemic corticosteroids); use low initial doses and increase the dose gradually. Increased risk of seizure w/ use of illicit drugs (eg, cocaine), abuse or misuse of prescription drugs (eg, CNS stimulants), use of oral hypoglycemic drugs or insulin, use of anorectic drugs, and excessive use of alcohol, benzodiazepines, sedative/hypnotics, or opiates. Ritonavir, lopinavir, or efavirenz may decrease exposure; may need to increase bupropion dose but not to exceed max dose. May reduce efficacy of drugs that require metabolic activation by CYP2D6 to be effective (eg, tamoxifen). CNS toxicity reported when coadministered w/ levodopa or amantadine; use w/ caution. Minimize or avoid alcohol. Monitor BP w/ nicotine replacement therapy. Potential for drug interactions w/ CYP2B6 inhibitors/inducers. Increased risk of HTN w/ MAOIs or other drugs that increase dopaminergic or noradrenergic activity. May increase exposure of CYP2D6 substrates (eg, antidepressants, antipsychotics, β-blockers, and type 1C antiarrhythmics [eg, propafenone, flecainide]); may need to decrease the dose of CYP2D6 substrates, particularly for drugs w/ a narrow therapeutic index. CYP2B6 inhibitors (eg, ticlopidine, clopidogrel) may increase bupropion exposure but decrease hydroxybupropion exposure; may need to adjust dose. Carbamazepine, phenytoin, and phenobarbital may induce metabolism and decrease exposure. If used concomitantly w/ a CYP inducer, may need to increase the dose of bupropion, but not to exceed the max dose.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Aminoketone antidepressant; has not been established. Weak inhibitor of the neuronal reuptake of norepinephrine and dopamine. Presumed that action is mediated by noradrenergic and/or dopaminergic mechanisms.

PHARMACOKINETICS

Absorption: T_{max}=3 hrs, 6 hrs (hydroxybupropion). **Distribution:** Plasma protein binding (84%); found in breast milk. **Metabolism:** Extensive. Hydroxylation (CYP2B6), reduction of carbonyl group; hydroxybupropion, threohydrobupropion, and erythrohydrobupropion (active metabolites). **Elimination:** Urine (87%), feces (10%), (0.5% unchanged); $T_{1/2}$=21 hrs, 20 hrs, 33 hrs, 37 hrs (bupropion, hydroxybupropion, erythrohydrobupropion, threohydrobupropion, respectively).

ASSESSMENT

Assess for bipolar disorder, hepatic/renal dysfunction, seizure disorders or conditions that may increase risk of seizure, susceptibility to angle-closure glaucoma, hypersensitivity to the drug, and any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, BP, and for possible drug interactions.

MONITORING

Monitor for clinical worsening, suicidality, or unusual changes in behaviors, neuropsychiatric symptoms, seizures, BP, activation of mania or hypomania, psychosis and other neuropsychiatric reactions, angle-closure glaucoma, anaphylactoid/anaphylactic reactions, delayed hypersensitivity, and other adverse reactions. Monitor hepatic/renal function, especially in elderly. Periodically reassess the appropriate dose and the need for maint treatment.

PATIENT COUNSELING

Inform of benefits/risks of therapy. Advise patients and caregivers of need for close observation for clinical worsening and/or suicidal risks. Educate on the symptoms of hypersensitivity and to d/c if a severe allergic reaction occurs. Instruct to d/c and not restart if a seizure occurs while on therapy. Inform that therapy may impair mental/physical abilities; advise to use caution while operating hazardous machinery/driving. Inform that

excessive use or abrupt discontinuation of alcohol or sedatives may alter the seizure threshold; advise to minimize or avoid alcohol use. Instruct to notify physician if taking/planning to take any prescription or OTC medications. Advise not to use therapy in combination w/ other medicines containing bupropion hydrochloride. Advise to contact physician if pregnancy occurs or is intended during therapy. Caution about the risk of angle-closure glaucoma in susceptible patients.

STORAGE

20-25°C (68-77°F); excursions permitted 15-30°C (59-86°F). Protect from light and moisture.

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