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Paxil (paroxetine hydrochloride) - Drug Summary

Apotex Corp.

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Paxil
(paroxetine hydrochloride)

BOXED WARNING

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders. Monitor and observe closely for clinical worsening, suicidality, or unusual changes in behavior in patients who are started on antidepressants. Not approved for use in pediatric patients.

THERAPEUTIC CLASS

Selective serotonin reuptake inhibitor (SSRI)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Major Depressive Disorder

Initial: 20mg/day
Titrate: May increase in 10mg/day increments at intervals of at least 1 week
Maint: Efficacy is maintained for periods of up to 1 yr w/ doses that averaged about 30mg
Max: 50mg/day

Obsessive Compulsive Disorder

Initial: 20mg/day
Titrate: May increase in 10mg/day increments at intervals of at least 1 week
Recommended: 40mg/day
Max: 60mg/day

Panic Disorder

W/ or w/o Agoraphobia:
Initial: 10mg/day
Titrate: May increase in 10mg/day increments at intervals of at least 1 week
Target Dose: 40mg/day
Max: 60mg/day

Anxiety Disorders

Social Anxiety Disorder:
Initial/Usual: 20mg/day
Titrate: May increase in 10mg/day increments at intervals of at least 1 week
Range: 20-60mg/day; no additional benefit for doses >20mg/day

Generalized Anxiety Disorder:
Initial/Usual: 20mg/day
Titrate: May increase in 10mg/day increments at intervals of at least 1 week
Range: 20-50mg/day

Post-traumatic Stress Disorder

Initial: 20mg/day
Titrate: May increase in 10mg/day increments at intervals of at least 1 week
Range: 20-50mg/day

Dosing Considerations with MAOIs

Switching to/from an MAOI for Psychiatric Disorders:
Allow at least 14 days between discontinuation of an MAOI and initiation of treatment, and conversely allow at least 14 days between discontinuing treatment before starting an MAOI

Use w/ Other MAOIs (eg, Linezolid, IV Methylene Blue):
If acceptable alternatives are not available and benefits outweigh risks of serotonin syndrome, d/c paroxetine promptly and administer linezolid or IV methylene blue; monitor for serotonin syndrome for 2 weeks or until 24 hrs after last dose of linezolid or IV methylene blue, whichever comes 1st.
May resume paroxetine therapy 24 hrs after last dose of linezolid or IV methylene blue

DOSING CONSIDERATIONS

Renal Impairment
Initial: 10mg/day
Max: 40mg/day

Severe Hepatic Impairment
Initial: 10mg/day
Max: 40mg/day

Elderly
Elderly/Debilitated:
Initial: 10mg/day
Max: 40mg/day

Discontinuation
Reduce gradually; consider resuming previously prescribed dose if intolerable symptoms occur following a decrease in dose or upon discontinuation. Subsequently, may continue to decrease the dose, but at a more gradual rate

ADMINISTRATION

Oral route

Take w/ or w/o food
Give qd, usually in the am

Tab
Swallow whole; do not chew or crush

Sus
Shake well before use

HOW SUPPLIED

Sus: 10mg/5mL [250mL]; Tab: 10mg*, 20mg*, 30mg, 40mg *scored

CONTRAINDICATIONS

Use of an MAOI for psychiatric disorders either concomitantly or within 14 days of stopping treatment. Treatment within 14 days of stopping an MAOI for psychiatric disorders. Starting treatment in a patient being treated with other MAOIs (eg, linezolid, IV methylene blue). Concomitant use with thioridazine or pimozide.

WARNINGS/PRECAUTIONS

May precipitate mixed/manic episode in patients at risk for bipolar disorder. Not approved for treatment of bipolar depression. Serotonin syndrome reported; d/c immediately and initiate supportive symptomatic treatment. Pupillary dilation that occurs following use may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Increased risk of congenital malformations reported in 1st trimester of pregnancy; neonates exposed to therapy late in the 3rd trimester have developed complications. Activation of mania/hypomania reported; caution with history of mania. Seizures reported; d/c if seizures develop. Adverse reactions reported upon discontinuation; avoid abrupt withdrawal. Akathisia may develop. Hyponatremia may occur; caution in elderly and volume-depleted patients. Consider discontinuation in patients with symptomatic hyponatremia and institute appropriate medical intervention. May increase risk of bleeding events. Bone fracture risk following exposure to some antidepressants reported. Caution with diseases/conditions affecting hemodynamic responses or metabolism, severe hepatic/renal impairment, and in elderly/debilitated patients. Mydriasis reported; caution with narrow-angle glaucoma.

ADVERSE REACTIONS

Asthenia, nausea, somnolence, headache, insomnia, abnormal ejaculation, dry mouth, constipation, dizziness, diarrhea, decreased libido, sweating, decreased appetite, tremor, impotence.

DRUG INTERACTIONS

See Contraindications. Not recommended with SSRIs, SNRIs, tryptophan, and alcohol. May cause serotonin syndrome with other serotonergic drugs (eg, triptans, TCAs, fentanyl) and with drugs that impair metabolism of serotonin; d/c immediately if this occurs. Metabolism and pharmacokinetics may be affected by the induction or inhibition of drug-metabolizing enzymes. Increased risk of bleeding with aspirin, NSAIDs, warfarin, and other anticoagulants. Increased risk of hyponatremia with diuretics. Increased levels with cimetidine. Decreased levels with phenobarbital, phenytoin, and fosamprenavir/ritonavir. Caution with drugs that are metabolized by CYP2D6 (eg, phenothiazines, risperidone, type 1C antiarrhythmics) and with drugs that inhibit CYP2D6 (eg, quinidine). May increase levels of desipramine, risperidone, procyclidine and theophylline. May increase levels of atomoxetine; may require dose adjustments of atomoxetine. May inhibit metabolism of TCAs. May displace or be displaced by other highly protein-bound drugs. May reduce efficacy of tamoxifen. Caution with warfarin, TCAs, lithium, and digoxin. Severe hypotension reported when added to chronic metoprolol treatment.

PREGNANCY AND LACTATION

Category D, caution in nursing.

MECHANISM OF ACTION

SSRI; inhibits CNS neuronal reuptake of serotonin.

PHARMACOKINETICS

Absorption: Complete; C_{max}=61.7ng/mL, T_{max}=5.2 hrs (tab 30mg). **Distribution:** Plasma protein binding (95% [100ng/mL], 93% [400ng/mL]); found in breast milk. **Metabolism:** Extensive; oxidation and methylation via CYP2D6. **Elimination:** Urine (62% metabolites; 2% parent compound); feces (36%, <1% parent compound) (30mg oral sol); $T_{1/2}$=21 hrs (tab 30mg).

ASSESSMENT

Assess for drug hypersensitivity, risk of bipolar disorder, history of seizures or mania, volume depletion, diseases/conditions that affect metabolism or hemodynamic responses, hepatic/renal impairment, susceptibility to angle-closure glaucoma or narrow-angle glaucoma, pregnancy/nursing status, and for possible drug interactions.

MONITORING

Monitor for signs/symptoms of clinical worsening, suicidality, unusual changes in behavior, serotonin syndrome, angle-closure glaucoma, seizures, activation of mania/hypomania, akathisia, bone fracture, hyponatremia especially in the elderly, abnormal bleeding, and other adverse reactions. Periodically reevaluate long-term usefulness of therapy.

PATIENT COUNSELING

Inform about benefits, risks, and appropriate use of therapy. Caution about risk of serotonin syndrome, angle-closure glaucoma, and bleeding. Counsel to be alert for emergence of unusual changes in behavior, worsening of depression, and suicidal ideation, especially during drug initiation or dose adjustment. Caution against operating hazardous machinery (including automobiles) until reasonably certain that therapy does not adversely affect ability to engage in such activities. Inform that improvement may be noticed in 1-4 weeks; instruct to continue therapy ud. Inform physician if taking, or planning to take, any prescription or OTC drugs. Instruct to notify physician if pregnant/intending to become pregnant, or if breastfeeding. Advise to avoid alcohol.

STORAGE

Tab: 15-30°C (59-86°F). Sus: ≤25°C (77°F).

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