Trazodone Hydrochloride (trazodone hydrochloride) - Drug Summary

Apotex Corp.

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Trazodone
(trazodone 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. Not approved for use in pediatric patients.

THERAPEUTIC CLASS

Triazolopyridine derivative

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Major Depressive Disorder

Initial: 150mg/day in divided doses
Titrate: Increase by 50mg/day every 3-4 days
Max:
Outpatient: 400mg/day in divided doses
Inpatient: 600mg/day in divided doses

Once adequate response is achieved, gradually reduce dose, w/ subsequent adjustment depending on therapeutic response; continue treatment for several months after initial response

DOSING CONSIDERATIONS

Adverse Reactions
Drowsiness: Administer major portion of daily dose hs or reduce dose

ADMINISTRATION

Oral route

Take shortly after a meal or light snack
Swallow tab whole or administer as a 1/2 tab by breaking along the score line

HOW SUPPLIED

Tab: 50mg*, 100mg*, 150mg*, 300mg* *scored

WARNINGS/PRECAUTIONS

Monitor for withdrawal symptoms when discontinuing treatment; gradually reduce dose. May cause serotonin syndrome or neuroleptic malignant syndrome (NMS)-like reactions; d/c immediately and initiate supportive symptomatic treatment. May precipitate a mixed/manic episode in patients at risk for bipolar disorder; screen for risk of bipolar disorder prior to initiating treatment. Not approved for treatment of bipolar depression. May cause QT/QTc interval prolongation, torsades de pointes, cardiac arrhythmias, and hypotension, including orthostatic hypotension and syncope. Not recommended for use during initial recovery phase of MI. May increase risk of bleeding events. Priapism reported; caution in men with conditions that may predispose to priapism (eg, sickle cell anemia, multiple myeloma, leukemia) or with penile anatomical deformation; d/c with erection lasting >6 hrs

(painful or not). Hyponatremia may occur; caution in elderly and volume-depleted patients. Consider discontinuation in patients with symptomatic hyponatremia and institute appropriate medical intervention. May cause somnolence or sedation and may impair mental/physical abilities. 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. Caution with cardiac disease, hepatic/renal impairment, and in elderly.

ADVERSE REACTIONS

Somnolence/sedation, dizziness, constipation, blurred vision, dry mouth, headache, nervousness, N/V, fatigue, abdominal/gastric disorder, nasal/sinus congestion, musculoskeletal aches/pains.

DRUG INTERACTIONS

May cause serotonin syndrome or NMS-like reactions with other serotonergic drugs (eg, SSRIs, SNRIs, triptans), drugs that impair serotonin metabolism (eg, MAOIs), antipsychotics, or other dopamine antagonists; d/c immediately if these occur. Caution with other drugs that may affect the neurotransmitter systems. Not recommended with serotonin precursors (eg, tryptophan). CYP3A4 inhibitors (eg, ritonavir, ketoconazole, indinavir) may increase levels with the potential for adverse effects. Potent CYP3A4 inhibitors may increase risk of cardiac arrhythmia; consider lower dose of trazodone. CYP3A4 inducers (eg, carbamazepine) may decrease levels; monitor to determine if a trazodone dose increase is required. Increased serum digoxin or phenytoin levels reported; monitor serum levels and adjust dosages as needed. Should not be used with an MAOI or within 14 days of discontinuing an MAOI; allow at least 14 days after stopping trazodone before starting an MAOI. May enhance response to alcohol, barbiturates, and other CNS depressants. May alter PT in patients on warfarin. Concomitant use with an antihypertensive may require a dose reduction of the antihypertensive drug. Monitor for potential risk of bleeding and use caution with NSAIDs, aspirin, and other drugs that affect coagulation or bleeding. Increased risk of hyponatremia with diuretics. Increased risk of cardiac arrhythmia with drugs that prolong QT interval or CYP3A4 inhibitors.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Triazolopyridine derivative; not established. Suspected to be related to its potentiation of serotonergic activity in the CNS. Preclinical studies show selective inhibition of neuronal reuptake of serotonin and activity as an antagonist at 5-HT-2A/2C serotonin receptors. Antagonizes α1-adrenergic receptors.

PHARMACOKINETICS

Absorption: Well-absorbed; T_{max}=1 hr (fasted), 2 hrs (fed). **Distribution:** Plasma protein binding (89%-95%). **Metabolism:** Liver (extensive); oxidative cleavage via CYP3A4; m-chlorophenylpiperazine (active metabolite). **Elimination:** Urine (<1% unchanged).

ASSESSMENT

Assess for risk for bipolar disorder, cardiac disease (eg, recent MI), conditions that may predispose to priapism, penile anatomical deformation, volume depletion, susceptibility to angle-closure glaucoma, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of clinical worsening, suicidality, unusual changes in behavior, mania/hypomania, serotonin syndrome, NMS-like reactions, QT/QTc interval prolongation, cardiac arrhythmias, hypotension, syncope, bleeding events, priapism, hyponatremia, angle-closure glaucoma, withdrawal symptoms, and other adverse reactions. Periodically reassess to determine the continued need for maintenance treatment.

PATIENT COUNSELING

Inform of the risks, benefits, and appropriate use of therapy. Instruct patients and caregivers to notify physician if signs of clinical worsening, changes in behavior, or suicidality occur. Instruct to report to physician the occurrence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, or mania. Instruct to inform physician if patient has history of bipolar disorder, cardiac disease, or MI. Caution about the risks of serotonin syndrome, angle-closure glaucoma, priapism, hypotension, syncope, bleeding, and withdrawal symptoms. Instruct men to immediately d/c use and seek emergency medical attention if erection lasts >6 hrs, whether painful or not. Caution against performing potentially hazardous tasks (eg, operating machinery) until reasonably certain that treatment does not affect them. Inform that therapy may enhance response to alcohol. Instruct to notify physician if intending to become pregnant, or breastfeeding.

STORAGE

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

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