Pristiq (desvenlafaxine) - Drug Summary

Wyeth Pharmaceuticals Company, a subsidiary of Pfizer Inc.

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Pristiq (desvenlafaxine)

BOXED WARNING

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. Monitor and observe closely for worsening, and emergence of suicidal thoughts and behaviors. Not approved for use in pediatric patients.

THERAPEUTIC CLASS

Serotonin and norepinephrine reuptake inhibitor (SNRI)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Major Depressive Disorder

50mg qd

50-400mg/day were effective; no additional benefit at doses >50mg/day and more frequent adverse reactions reported at higher doses

Switching from Other Antidepressants:
May need to taper initial antidepressant

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 desvenlafaxine, and allow at least 7 days between discontinuation of desvenlafaxine and initiation of an MAOI

W/ Other MAOIs (eg, Linezolid, IV Methylene Blue):
Do not start desvenlafaxine in a patient being treated w/ linezolid or IV methylene blue
In patients already receiving desvenlafaxine, if acceptable alternatives are not available and benefits outweigh risks, d/c desvenlafaxine promptly and administer linezolid or IV methylene blue; monitor for serotonin syndrome for 7 days or until 24 hrs after the last dose of linezolid or IV methylene blue, whichever comes 1st. May resume desvenlafaxine therapy 24 hrs after the last dose of linezolid or IV methylene blue

DOSING CONSIDERATIONS

Renal Impairment
Moderate (CrCl 30-50mL/min):
Max: 50mg/day
Severe (CrCl <30mL/min)/ESRD:
Max: 25mg qd or 50mg qod; do not give supplemental doses after dialysis

Hepatic Impairment
Moderate to Severe:
Usual: 50mg/day
Max: Dose escalation >100mg/day not recommended

Discontinuation
Gradually reduce dose; if intolerable symptoms occur following a decrease in dose or upon discontinuation, consider resuming the previously prescribed dose and continue decreasing the dose at a more gradual rate. The 25mg dose is available for discontinuing therapy

ADMINISTRATION

Oral route

Take at approx the same time each day, w/ or w/o food
Swallow tab whole w/ fluid; do not divide, crush, chew, or dissolve

HOW SUPPLIED

Tab, Extended-Release: 25mg, 50mg, 100mg

CONTRAINDICATIONS

Use of an MAOI intended to treat psychiatric disorders either concomitantly or w/in 7 days of stopping treatment. Treatment w/in 14 days of stopping an MAOI to treat psychiatric disorders. Starting treatment in patients being treated w/ other MAOIs (eg, linezolid, IV methylene blue).

WARNINGS/PRECAUTIONS

Not approved for the treatment of bipolar depression. Serotonin syndrome reported; d/c immediately if symptoms occur and initiate supportive symptomatic treatment. Caution w/ preexisting HTN or cardiovascular (CV)/cerebrovascular conditions that might be compromised by increases in BP. Consider dose reduction or discontinuation of therapy if sustained increases in BP occur. May increase risk of bleeding events. 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. Activation of mania/hypomania reported. Discontinuation symptoms reported. Avoid abrupt discontinuation. Seizures reported. Hyponatremia may occur; caution in elderly and volume-depleted patients. Consider discontinuation in patients w/ symptomatic hyponatremia. Interstitial lung disease and eosinophilic pneumonia may occur; consider diagnosis for either in patients w/ progressive dyspnea, cough, or chest discomfort, and consider discontinuing therapy. False (+) urine immunoassay screening tests for phencyclidine and amphetamines reported.

ADVERSE REACTIONS

N/V, dry mouth, dizziness, insomnia, somnolence, hyperhidrosis, constipation, anxiety, decreased appetite, tremor, mydriasis, erectile dysfunction, anorgasmia, fatigue, vision blurred.

DRUG INTERACTIONS

See Contraindications. Avoid w/ other desvenlafaxine-containing products or venlafaxine products; may increase levels and increase dose-related adverse reactions. Avoid alcohol consumption. May cause serotonin syndrome w/ other serotonergic drugs (eg, triptans, TCAs, fentanyl) and w/ drugs that impair metabolism of serotonin; d/c desvenlafaxine and any concomitant serotonergic agent immediately if serotonin syndrome occurs. Caution w/ NSAIDs, aspirin (ASA), warfarin, and other drugs that affect coagulation or bleeding, due to increased risk of bleeding. May increase risk of hyponatremia w/ diuretics. Potent CYP3A4 inhibitors (eg, ketoconazole) may increase levels. CYP2D6 substrates (eg, desipramine, atomoxetine, dextromethorphan) should be dosed at the original level when coadministered w/ 100mg desvenlafaxine or lower, or when desvenlafaxine is discontinued; reduce the dose of these substrates by up to 1/2 if coadministered w/ 400mg of desvenlafaxine.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

SNRI; has not been established. Thought to be related to the potentiation of serotonin and norepinephrine in the CNS through inhibition of their reuptake.

PHARMACOKINETICS

Absorption: Absolute bioavailability (80%). **Distribution:** Plasma protein binding (30%); V_d=3.4L/kg (IV); found in breast milk. **Metabolism:** Conjugation via UGT isoforms (primary) and N-demethylation via CYP3A4 (minor). **Elimination:** Urine (45% unchanged, 19% glucuronide metabolite, <5% oxidative metabolite). $T_{1/2}$=10-11.1 hrs.

ASSESSMENT

Assess for risk for bipolar disorder, history of mania/hypomania, seizure disorders, HTN, CV/cerebrovascular conditions, susceptibility to angle-closure glaucoma, volume depletion, hypersensitivity to the drug, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of clinical worsening (eg, suicidality, unusual changes in behavior), serotonin syndrome, abnormal bleeding, angle-closure glaucoma, activation of mania/hypomania, seizures, hyponatremia, interstitial lung disease, eosinophilic pneumonia, and other adverse reactions. Monitor BP, LFTs, and renal function. Monitor for discontinuation symptoms (eg, dysphoric mood, irritability, agitation) when discontinuing therapy. Carefully monitor patients receiving concomitant warfarin therapy when treatment w/ desvenlafaxine is initiated or discontinued. Periodically reassess to determine the need for continued treatment.

PATIENT COUNSELING

Advise patients, families, and caregivers about the benefits and risks of treatment and counsel on its appropriate use. Counsel patients, families, and caregivers to look for the emergence of suicidality, especially early during treatment and when the dose is adjusted up or down. Caution about the risk of serotonin syndrome, particularly w/ the concomitant use w/ other serotonergic agents. Inform that concomitant use w/ ASA, NSAIDs, warfarin, or other drugs that affect coagulation may increase the risk of bleeding. Advise to monitor BP regularly, to observe for signs/symptoms of activation of mania/hypomania, to avoid alcohol, and not to d/c therapy w/o notifying physician. Inform that discontinuation effects may occur when stopping treatment and a dose of 25mg/day is

available for discontinuing therapy. Caution about risk of angle-closure glaucoma. Caution against operating hazardous machinery (including automobiles) until reasonably certain that therapy does not adversely affect ability to engage in such activities. Advise to notify physician if allergic phenomena develop, if pregnant, intending to become pregnant, or if breastfeeding. Inform that an inert matrix tab may pass in the stool or via colostomy.

STORAGE

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

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