paroxetine, low dose  (par-ox-e-teen)

Indications
Therapeutic: antidepressants
Pharmacologic: selective serotonin reuptake inhibitors (SSRIs)

Pregnancy Category X

Indications
Moderate to severe vasomotor symptoms (VMS) associated with menopause.

Action
Inhibits neuronal reuptake of serotonin in the CNS, thus potentiating the activity of serotonin; has little effect on norepinephrine or dopamine.

Therapeutic Effects:
Decreased symptoms of VMS.

Pharmacokinetics
Absorption:
Completely absorbed following oral administration.

Distribution:
Widely distributed throughout body fluids and tissues, including the CNS; cross the placenta and enter breast milk.

Protein Binding:
95%.

Metabolism and Excretion:
Highly metabolized by the liver (partly by P450 2D6 enzyme system); the CYP2D6 enzyme system exhibits genetic polymorphism; 7% of population may be poor metabolizers (PMs) and may have significantly higher paroxetine concentrations and an increased risk of adverse effects. 2% excreted unchanged in urine.

Half-life: 21 hr.

TIME/ACTION PROFILE (improvement in VMS)
ROUTE ONSET PEAK DURATION
PO within 4 wk unk unk

Contraindications/Precautions
Contraindicated in: Hypersensitivity; Concurrent MAO inhibitor, linezolid, methylene blue, thioridazine, or pimozide therapy; OB: Use during the first trimester may be associated with an increased risk of cardiac malformations—consider fetal risk/benefit; use during third trimester may result in neonatal serotonin syndrome requiring prolonged hospitalization, respiratory and nutritional support; avoid use during pregnancy.

Use Cautiously in: Risk of suicide (may increase risk of suicide attempt/ideation especially during early treatment or dose adjustment); History of bipolar disorder; Lactation: Safety not established; discontinue drug or bottle feed; Pedi: May increase risk of suicide attempt/ideation especially during early treatment or dose adjustment; may be greater in children and adolescents (safety in children/adolescents not established); Geri: Severe renal/hepatic impairment, geriatric or debilitated patients (daily dose should not exceed 40 mg); history of mania/risk of suicide.

Adverse Reactions/Side Effects

Interactions
Drug-Drug: Serious, potentially fatal reactions (hyperthermia, rigidity, myoclonus, autonomic instability, with fluctuating vital signs and extreme agitation, which may proceed to delirium and coma) may occur with concurrent MAO inhibitor therapy (including linezolid and methylene blue). MAO inhibitors should be stopped at least 14 days prior to paroxetine therapy. Paroxetine should be stopped at least 14 days prior to MAO inhibitor therapy. May decrease metabolism of certain drugs that are metabolized by the liver, including other antidepressants, phenothiazines, class IC antiarrhythmics, oxcarbazepine, theophylline, procyclidine, and quinidine. Concurrent use should be undertaken with caution. Concurrent use with pimozide or thioridazine may increase risk of QT interval prolongation and torsades de pointes; concurrent use contraindicated. Concomitant use with 5-HT1 agonists (frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan), fentanyl, lithium, or tramadol may result in increased serotonin levels and lead to serotonin syndrome.

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Drugs-Natural Products

7 Risk of serotonergic side effects including serotonin syndrome with St. John’s wort, SAMe, and tryptophan.

Route/Dosage
PO (Adults): 7.5 mg once daily.

NURSING IMPLICATIONS

Assessment

● Used only for vasomotor symptoms, not depression or bipolar disorder. Assess patient for signs and symptoms of bipolar disorder with a detailed psychiatric history, including family history of suicide, bipolar disorder, and depression prior to starting therapy.

● Assess for suicidal tendencies, especially during early therapy. Restrict amount of drug available to patient. Risk may be increased in children, adolescents, and adults ≥ 24 yr.

● Assess for serotonin syndrome (mental changes [agitation, hallucinations, coma], autonomic instability [tachycardia, labile BP, hyperthermia], neuromuscular alterations [hyperreflexia, incoordination], and/or 4d symptoms [nausea, vomiting, diarrhea]), especially in patients taking other serotonergic drugs (SSRIs, SNRIs, triptans, St. John’s Wort, tramadol).

● Lab Test Considerations: May cause hyponatremia. Monitor serum sodium levels and symptoms of 4d.

Potential Nursing Diagnoses

Deficient knowledge, related to medication regimen: Patient/Family Teaching

Implementation

PO:Administer at bedtime with or without food.

Patient/Family Teaching

● Instruct patient to take paroxetine as directed. Take missed doses as soon as possible, unless almost time for next dose; do not double doses. Advise patient to read Medication Guide before starting and with each Rx refill in case of changes.

● May cause drowsiness or dizziness. Caution patient to avoid driving and other activities requiring alertness until response to the drug is known.

● Instruct patient of risk of increased fractures with paroxetine.

● Advise patient, family, and caregivers to look for suicidality, especially during early therapy or dose changes. Notify health care professional immediately if thoughts about suicide or dying, attempts to commit suicide, new or worse depression or anxiety, agitation or restlessness, panic attacks, insomnia, new or worse irritability, aggressiveness, being on dangerous impulses, mania, or other changes in mood or behavior or if symptoms of serotonin syndrome or neuroleptic malignant syndrome occur.

● Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and consult health care professional before taking any new medications and to avoid alcohol or other CNS-depressant drugs during therapy.

● Advise patient to notify health care professional if signs and symptoms of hyperthermia (difficulty concentrating, memory impairment, confusion, weakness, and faintness) or restlessness (inner restlessness, agitation, nervousness, or inability to sit still or stand still, especially at beginning of therapy) occur or if head- ache, fatigue, nausea, and vomiting persist.

● Instruct female patient to inform health care professional if pregnancy is planned or suspected or if breast feeding.

Evaluation/Desired Outcomes

● Reduction of moderate to severe hot flashes associated with menopause.

Why was this drug prescribed for your patient?