**PAROXETINE ADVERSE REACTIONS MAY INCLUDE:** per PDR

**Severe:** visual impairment, muscle paralysis, bradycardia, angioedema, anaphylactoid reactions, bronchospasm, keratoconjunctivitis, pancreatitis, proteinuria, peptic ulcer, hematemesis, GI obstruction, ileus, akinesia, torticollis, coma, myelitis, seizures, myocardial infarction, stroke, atrial fibrillation, heart failure, pulmonary embolism, thrombosis, erythema nodosum, erythema multiforme, exfoliative dermatitis, pulmonary fibrosis, pulmonary edema, hearing loss, retinal hemorrhage, ocular hypertension, ocular hemorrhage, oliguria, epididymitis, hyperkalemia, laryngospasm, Guillain-Barre syndrome, SIADH, vasculitis, agranulocytosis, aplastic anemia, GI bleeding, pancytopenia, hemolytic anemia, ventricular fibrillation, torsade de pointes, ventricular tachycardia, pulmonary hypertension, toxic epidermal necrolysis, Stevens-Johnson syndrome, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), optic neuritis, hepatic necrosis, porphyria, renal failure (unspecified), serotonin syndrome, bone fractures, teratogenesis, neonatal abstinence syndrome, persistent pulmonary hypertension of the newborn

**Moderate:** ejaculation dysfunction, constipation, impotence (erectile dysfunction), peripheral vasodilation, blurred vision, hypertension, myoclonia, chest pain (unspecified), palpitations, dysuria, amnesia, memory impairment, hypertension, sinus tachycardia, myopathy, teeth grinding (bruxism), stomatitis, colitis, dysphagia, melena, gastritis, hemorrhoids, dyskinesia, dystonic reaction, nyctagmus, ataxia, neuropathic pain, confusion, migraine, lymphadenopathy, anemia, leukopenia, eosinophilia, hemotoma, orthostatic hypotension, hypotension, supraventricular tachycardia (SVT), angina, edema, contact dermatitis, atopic dermatitis, dyspnea, conjunctivitis, elevated hepatic enzymes, vaginitis, urinary retention, pyuria, urinary incontinence, cystitis, myasthenia, peripheral edema, oral ulceration, sialadenitis, gingival hyperplasia, glossitis, choledolithiasis, fecal incontinence, esophagitis, choreoathetosis, dysarthria, trismus, hyperalgesia, hyperreflexia, meningitis, aphasia, neuritis, hyponatremia, thrombocytopenia, lymphopenia, prolonged bleeding time, lymphocytosis, bundle-branch block, phlebitis, candidiasis, furunculosis, skin ulcer, bullous rash, hemoptysis, dysphonia, ambylophia, blepharitis, hyperacusis, cataracts, exophthalmos, photophobia, hyperbilirubinemia, jaundice, hepatitis, vaginal bleeding, prostatitis, nephrolithiasis, flank pain, tetany, hypothyroidism, hyperthyroidism, diabetes mellitus, goiter, hyperglycemia, hypoglycemia, hypercalcemia, hypokalemia, hypercholesterolemia, hypocalcemia, gout, dehydration, hyperphosphatemia, osteoporosis, withdrawal, akathisia, bleeding, platelet dysfunction, pneumonitis, hepatomegaly, hyperprolactinemia, priapism, galactorrhea, hematuria, osteopenia, growth inhibition

**Mild:** headache, nausea, insomnia, drowsiness, asthenia, diarrhea, xerostomia, dizziness, libido decrease, tremor, hyperhidrosis, anorexia, orgasm dysfunction, sinusitis, infection, abdominal pain, flatulence, dyspepsia, yawning, dysmenorrhea, back pain, myalgia, malaise, fatigue, lethargy, appetite stimulation, paresthesias, pharyngitis, rhinitis, weight gain, vomiting, rash. increased urinary frequency, chills, cough, fever, dysgeusia, arthralgia, gingivitis, dental pain, eructation, gastroesophageal reflux, weight loss, hyperkinesis, vertigo, hypoesthesia, purpura, leukocytosis, ecchymosis, syncope, photosensitivity, acne vulgaris, urticaria, xerosis, alopecia, hyperventilation, laryngitis, ocular pain, mydriasis, otalgia, amenorrhea, ibid increase, menorrhagia, urinary urgency, polyuria, nocturia, polydipsia, dental caries, tongue discoloration, hyporeflexia, palor, hypothermia, skin discoloration, seborrhea, vesicular rash, maculopapular rash, hirsutism, hiccup, diplopia, parosmia, ptosis, gynecomastia, leukorrhea, mastalgia, breast enlargement, breast discharge, pelvic pain, muscle cramps, pruritus, tinnitus, restless legs syndrome (RLS), petechiae
PAROXETINE SIDE EFFECTS MAY INCLUDE:
abnormal dreams, abnormal ejaculation or orgasm, anxiety, appetite loss, blurred vision, chills, constipation, diarrhea, dizziness, dry mouth, frequent urination, flushing, gas, headache, impotence, infection, insomnia, muscle tension, nausea, nervousness, rash, sleepiness, sweating, tingling feeling, tremor, upset stomach, vomiting, weakness, yawning, abnormal taste, abnormal thinking, agitation, chest pain, confusion, decreased sex drive, depression, dilated pupils, dizziness upon standing up, high blood pressure, itching, loss of identity, rapid heartbeat, ringing in the ears, trauma, twitching, urinary problems, weight loss

PAROXETINE BOXED WARNINGS: per PDR
Children, growth inhibition, suicidal ideation

Paroxetine is not FDA-approved for use in children and adolescents less than 18 years of age. According to the FDA, there are 3 well-controlled trials that have shown paroxetine is no more effective than placebo for the treatment of depression in pediatric patients. In October 2004, the FDA directed manufacturers of all antidepressants to include a boxed warning detailing the risk of suicide in pediatric patients with MDD and other psychiatric disorders (OCD, social anxiety disorder). A causal role has been established for antidepressants in inducing suicidality in pediatric patients. The risk of suicidality for these drugs was identified in a pooled analysis of 24 placebo-controlled trials (n = 4,400) lasting up to 16 weeks in pediatric patients with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants (SSRIs and others). The average risk of such events on drug was 4% and 2% for placebo; however, no suicides occurred in these trials. Pooled analysis of short-term clinical trials during early phase treatment of SSRIs and other antidepressants in young adults (18 to 24 years) also showed an increased risk of suicidal thinking and behavior. The clinical need for an antidepressant in children or young adults for any use must be weighed against the risk of increased suicidality; patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior, particularly within the first few months of starting therapy or at the time of dose increase or decrease. It is unknown if the suicidality risk in children and young adults extends to longer-term therapy (i.e., beyond several months). In a meta-analysis conducted by the manufacturer in adult patients with and without psychiatric disorders, a higher frequency of suicidal behavior occurred in young adults and adults treated with paroxetine compared with placebo. This difference was statistically significant; however, as the number of events were small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with depression were non-fatal suicide attempts, and the majority of these attempts (8 of 11) were in younger adult patients. The possibility of a suicide attempt is inherent in all patients with depressive symptoms, whether these occur in primary depression or in association with another primary disorder such as OCD. All patients with a history of suicidal ideation or behaviors and those with a prominence of suicidal ideation prior to treatment are considered at an increased risk for suicidal ideation or attempts, and should be closely monitored during treatment with paroxetine. In patients who exhibit changes in symptoms, worsening of depression or suicidality, a decision should be made to change or discontinue treatment. If discontinuing, the medication should be tapered as rapidly as possible, but with recognition that abrupt discontinuation can also cause adverse symptoms. All antidepressants should be prescribed in the smallest quantity consistent with good patient management in order to reduce the risk of overdose. The potential for growth inhibition in pediatric patients should be monitored during SSRI therapy; monitor height and weight periodically. Data are inadequate to determine whether the chronic use of SSRIs causes long-term growth inhibition; however, decreased weight gain has been observed in children and adolescents receiving paroxetine.
Paroxetine Withdrawal Symptoms May Include:

aggression, anxiety, balance issues, blurred vision, brain zaps, concentration impairment, constipation, crying spells, depersonalization, diarrhea, dizziness, electric shock sensations, fatigue, flatulence, flu-like symptoms, hallucinations, hostility, highly emotional, indigestion, irritability, impaired speech, insomnia, jumpy nerves, lack of coordination, lethargy, migraine headaches / increased headaches, nausea, nervousness, over-reacting to situations, paranoia, repetitive thoughts or songs, sensory & sleep disturbances, severe internal restlessness (akathisia), stomach cramps, tremors, tinnitus (ear ringing or buzzing), tingling sensations, troubling thoughts, visual hallucinations / illusions, vivid dreams, speech or visual changes, worsened depression

Disclaimer:
*Because prescription medications can cause severe withdrawal reactions, do not stop taking any medication without first consulting your physician. The decision to taper any medication should be discussed with your doctor and done with their consent and support.
*While great care has been taken in organizing and presenting the material throughout this website, please note that it is provided for informational purposes only and should not be taken as Medical Advice.

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