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

**Severe:** visual impairment, tardive dyskinesia, suicidal ideation, arrhythmia exacerbation, heart failure, myocardial infarction, proteinuria, seizures, peptic ulcer, hematemesis, GI bleeding, pancreatitis, cholecytis, esophageal ulceration, GI obstruction, muscle paralysis, pulmonary hypertension, thrombosis, ventricular fibrillation, coronary vasospasm, stroke, atrial fibrillation, cardiac arrest, bradycardia, pneumothorax, apnea, pulmonary edema, laryngeal edema, ocular hypertension, hearing loss, oliguria, diabetic ketoacidosis, hyperkalemia, torticollis, thrombotic thrombocytopenic purpura (TTP, aplastic anemia, hemolytic anemia, SIADH, tordase de pointes, ventricular tachycardia, erythema nodosum, pulmonary fibrosis, lupus-like symptoms, bronchospasm, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, anaphylactoid reactions, angioedema, serum sickness, vasculitis, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), laryngospasm, toxic epidermal necrolysis, eosinophilic pneumonia, pulmonary embolism, optic neuritis, hepatic failure, hepatic necrosis, renal failure (unspecified), bone fractures, serotonin syndrome, persistent pulmonary hypertension of the newborn, neonatal abstinence syndrome.

**Moderate:** impotence (erectile dysfunction), ejaculation dysfunction, constipation, oral ulceration, melena, esophagitis, cholelithiasis, dysphagia, glossitis, gastritis, colitis, stomatitis, neuropathic pain, myoclonia, teeth grinding (bruxism), migraine, akathisia, ataxia, hypotonia, hostility, psychosis, euphoria, depression, anemia, hypotension, angina, orthostatic hypotension, peripheral edema, edema, vaginal bleeding, atopic dermatitis, skin ulcer, photophobia, conjunctivitis, elevated hepatic enzymes, urinary incontinence, dysuria, hematuria, urinary retention, cystitis, hypothyroidism, hypercholesterolemia, dehydration, hypokalemia, hyperlipidemia, gout, bone pain, synovitis, mania, abdominal pain, fecal incontinence, neuritis, hallucinations, EEG changes, dystonia, dysphagia, hyperglycemia, diabetes mellitus, hypoglycemia, osteopenia, bone fractures, serotonin syndrome, persistent pulmonary hypertension of the newborn, neonatal abstinence syndrome.

**Mild:** insomnia, nausea, headache, asthenia, diarrhea, anorexia, drowsiness, anxiety, tremor, xerostomia, yawning, libido decrease, dyspepsia, pharyngitis, dizziness, hyperhidrosis, urticaria, rash, sinusitis, abnormal dreams, flushing, flatulence, vomiting, pruritus, weight loss, epistaxis, fever, hypersalivation, polydipsia, eructation, paranoia, vertigo, hypoesthesia, ecchymosis, syncope, breast enlargement, orgasm dysfunction, mastalgia, menorrhagia, libido increase, breast discharge, amenorrhea, leukorrhea, photosensitivity, alopecia, maculopapular rash, skin discoloration, acne vulgaris, malaise, hyperterventilation, hiccups, mydriasis, xerophthalmia, polyuria, urinary urgency, nocturia, pelvic pain, arthralgia, muscle cramps, paresthesias, hyporeflexia, petechiae, purpura, pallor, hirsutism, seborrhea, parosmia, diplopia, appetite stimulation, weight gain, dysgeusia, emotional lability, hyperkinesia, agitation, hypothermia, chills, otalgia, tinnitus, increased urinary frequency, gynecomastia, influenza.
**FLUOXETINE SIDE EFFECTS MAY INCLUDE:**

- abnormal dreams
- abnormal ejaculation
- abnormal vision
- anxiety
- diminished sex drive
- dizziness
- dry mouth
- flu-like symptoms
- flushing
- gas
- headache
- impotence
- insomnia
- itching
- loss of appetite
- nausea
- nervousness
- rash
- sinusitis
- sleepiness
- sore throat
- sweating
- tremors
- upset stomach
- vomiting
- weakness
- yawning
- abnormal taste
- agitation
- bloating
- chills
- confusion
- ear pain
- emotional instability
- fever
- frequent urination
- high blood pressure
- increased appetite
- loss of memory
- palpitations
- ringing in the ears
- sleep disorders

**FLUOXETINE WITHDRAWAL SYMPTOMS MAY INCLUDE:**

- shaking
- confusion
- dizziness
- sweating
- severe headache
- insomnia
- anxiety
- burning or tingling sensations around the body
- brain zaps / brain shivers
- vertigo
- lightheadedness
- rushing noise in the head
- agitation
- negative
- tearful
- concentration problem
- tremors
- diarrhea
- vomiting
- reduced appetite
- nightmares
- excessive dreaming
- gastrointestinal issues

Double-blind controlled studies indicate that 35-78% of patients after five weeks or more of treatment who abruptly stop antidepressants or titrate in 10mg increments or more, will develop one of more of the discontinuation symptoms that can range from mild-moderate discomfort to extremely distressing. The duration of symptoms can vary in time between individuals and can include the following symptoms:

- Dizziness
- Vertigo
- Lightheadedness
- Difficulty walking
- Nausea / vomiting
- Fatigue
- Headaches
- Insomnia
- Shock-like sensations
- Parathesia (skin crawling, burning or prickling)
- Visual disturbances
- Muscle pain
- chills

**FLUOXETINE BOXED WARNINGS: per PDR**

**Children, growth inhibition, suicidal ideation**

Fluoxetine is approved for the treatment of depression in children 8 years of age and older, and for the treatment of obsessive-compulsive disorder (OCD) in children 7 years of age and older. The safety and effectiveness of fluoxetine in younger children have not been established. In October 2004, the FDA directed manufacturers of all antidepressants to include a boxed warning detailing the risk of suicide in pediatric patients. 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=4400) 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 with 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). The possibility of a suicide attempt is inherent in patients with depressive symptoms, whether these occur in primary depression or in association with another primary disorder. 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 fluoxetine. In patients who exhibit changes in symptoms, worsening of depression or emergent suicidality, a decision should be made to change or discontinue treatment. If discontinuing, 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 while the patient is receiving fluoxetine. 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 fluoxetine.
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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