Prozac

(fluoxetine)

Prozac (fluoxetine); not controlled

Full Prescribing Information	DailyMed Drug Information

Summary

Prozac is a selective serotonin reuptake inhibitor approved for major depressive disorder from 8 years of age and for obsessive-compulsive disorder from 7 years. Response is judged over weeks of continuous dosing. Its half-life is the longest in the class, so it is effectively self-tapering and forgiving of a missed dose. Not controlled; brand and generic.

Forms & Strengths

- **Capsules, immediate release:** 10 mg, 20 mg, 40 mg
- **Tablets:** 10 mg, 20 mg, 60 mg
- **Oral solution:** 20 mg/5 mL (4 mg/mL)
- **Capsule, delayed release, once weekly:** 90 mg. A separate label; NEVER studied in children
- **Olanzapine and fluoxetine capsules:** fluoxetine 25 mg or 50 mg with olanzapine 3, 6 or 12 mg

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Dosing

- **Age:**
  - MDD: 8 y/o and older
  - OCD: 7 y/o and older
  - Bipolar I depression, with olanzapine: 10 y/o and older
- **Onset:** 4 weeks or longer in MDD; 5 weeks or longer in OCD
- **Duration:** continuous with once-daily dosing

- **Initial Dose:**
  - Pediatric MDD: 10 or 20 mg/day; 10 mg/day if lower weight
  - Pediatric OCD: 10 mg/day at any weight
  - Adults: 20 mg/day
- **Titration:**
  - Pediatric MDD: to 20 mg/day after 1 week; OCD: to 20 mg/day after 2 weeks
  - Further increases only after several more weeks, never weekly
- **Max Dose:**
  - Ceiling at any age or indication: 80 mg/day
  - Pediatric OCD: 60 mg/day, or 30 mg/day if lower weight
  - Pediatric MDD: no separate maximum; trials used 10 to 20 mg/day
- **Considerations:** Give in the morning; a dose above 20 mg/day may be split between morning and noon. Use a lower or less frequent dose in cirrhosis.

Pharmacology

- **Mechanism:** Blocks presynaptic serotonin reuptake at SERT, without the tricyclics' anticholinergic and sedative burden
- **Delivery / Release:** immediate release; food does not affect bioavailability
- **Metabolism:** hepatic via CYP2D6 to active norfluoxetine. Half-life 4 to 6 days on chronic dosing, norfluoxetine 4 to 16 days, steady state at 4 to 5 weeks
- **Class Positioning:** a POTENT CYP2D6 inhibitor persisting up to 5 weeks after the last dose, unlike Zoloft. The only SSRI with a pediatric MDD indication

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Indications

- **Major Depressive Disorder** (ICD-10: F32.x, F33.x): 8 y/o and older
- **Obsessive-Compulsive Disorder** (ICD-10: F42.x): 7 y/o and older
- **Bulimia Nervosa** (ICD-10: F50.2): adults only, at 60 mg/day
- **Panic Disorder** (ICD-10: F41.0): adults only
- **Bipolar I depression, with olanzapine only** (ICD-10: F31.x): 10 y/o and older
- **Treatment-resistant depression, with olanzapine only**: adults

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Off-Label Uses

- **Pediatric anxiety disorders** (ICD-10: F41.1, F40.10, F93.0): supported; AHRQ graded SSRIs moderate to high, with CBT outperforming fluoxetine (AHRQ 2017). On-label alternative: Cymbalta from 7 y/o

- **MDD in CHILDREN rather than adolescents** (ICD-10: F32.x): graded low in adolescents, INSUFFICIENT in children (AACAP 2023)
- **Bulimia nervosa in adolescents** (ICD-10: F50.2): insufficient at any dose

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Contraindications & Warnings

- **Boxed Warning:** SUICIDAL THOUGHTS AND BEHAVIORS in children, adolescents and young adults.
  - Monitor closely for worsening and emergent suicidality in the initial few months and at every dose change, up or down.
  - Observation must include DAILY observation at home. Dispense the smallest quantity consistent with good management.
- **Contraindicated:**
  - An MAOI concurrently, within 5 WEEKS of stopping Prozac, or Prozac within 14 days of an MAOI. That 5-week exit washout is longer than the rest of the class, set by norfluoxetine's half-life.
  - Linezolid or intravenous methylene blue.
  - Pimozide and thioridazine; fluoxetine raises both via CYP2D6 and all three prolong QT.
- **Use with caution:**
  - Seizure history; long QT, hypokalemia, hypomagnesemia, recent myocardial infarction, heart failure, bradyarrhythmias.
  - Narrow angles without a patent iridectomy; diabetes; cirrhosis, needing a lower dose.
  - Underweight patients; NSAIDs, aspirin, anticoagulants, diuretics; prior rash on fluoxetine.
- **Screen before starting:**
  - Personal and family history of bipolar disorder, mania or hypomania; baseline height, weight and sexual function.
  - QT risk factors, and a medication list for CYP2D6 substrates, MAOIs and anticoagulants.

Drug Interactions

- **MAOIs** (phenelzine, selegiline, linezolid, methylene blue): contraindicated. 14 days before starting Prozac, 5 WEEKS after stopping it
- **CYP2D6 substrates including atomoxetine** (Strattera, TCAs, antipsychotics): start low, and treat anyone dosed within the previous 5 weeks as still on fluoxetine.
  - For atomoxetine, lengthen the titration interval to 4 weeks rather than lowering the target dose.
  - This pair, and Qelbree, stack two pediatric suicidality boxed warnings.

- **Bupropion** (Wellbutrin XL): doubles 2D6 inhibition and stacks seizure cautions
- **Other serotonergic drugs** (SSRIs, SNRIs, triptans, tramadol, lithium, AMPHETAMINES): serotonin syndrome. Stop all for agitation, hyperthermia, rigidity or myoclonus
- **Tricyclics, phenytoin, carbamazepine:** levels rise for weeks; check when fluoxetine starts and stops
- **NSAIDs, aspirin, warfarin:** bleeding; check the INR at both ends
- **QT-prolonging drugs** (ziprasidone, erythromycin, amiodarone, methadone): avoid, or obtain an ECG before each increase

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Administration

- Give once daily in the morning; split a dose above 20 mg for daytime nausea rather than reducing it.
- With or without food. Swallow capsules and tablets whole; the oral solution is the only form delivering below 10 mg.
- Missed dose: resume at the next dose; do not double up.
- Never use the 90 mg once-weekly capsule in a pediatric patient or in place of daily dosing.
- Switching to an MAOI: allow 5 weeks off fluoxetine. From an MAOI: allow 14 days.

Side Effects

- **Common:** nausea, insomnia, nervousness, somnolence, anxiety, diarrhea, anorexia, dry mouth, tremor, asthenia.
  - Pediatric trials add thirst, hyperkinesia, agitation, epistaxis, urinary frequency and menorrhagia.
- **Serious:**
  - Suicidal thoughts and behavior: the boxed warning. Change the regimen, including stopping, if suicidality emerges.
  - Serotonin syndrome: stop every serotonergic agent immediately and treat supportively.
  - Mania or hypomania, in 2.6% of pediatric patients. Stop and reassess for bipolar disorder.
  - Rash and systemic hypersensitivity. Discontinue on any unexplained rash.
  - Hyponatremia and SIADH; QT prolongation and torsades; seizures.
  - Growth lag: 1.1 cm and 1.1 kg below placebo at 19 weeks.
  - Bleeding; angle-closure glaucoma; sexual dysfunction.

Monitoring & Labs

- **Suicidality:** every visit for 3 months, at every dose change in either direction, then every 3 months. Instruct the family in DAILY home observation for the first month
- **Activation and mania:** screen for bipolar history before the first dose, then ask about reduced sleep need, pressured speech and elevated mood every 3 months
- **Growth:** plot height and weight at baseline, every 3 months for the first year, then every 6 months
- **Hyponatremia:** check sodium for new headache, confusion or unsteadiness, or when a diuretic is started
- **Bleeding:** ask about bruising and nosebleeds every 3 months; check the INR on warfarin
- **Response:** do not judge efficacy before 4 weeks in MDD or 5 weeks in OCD; reassess every 6 months, with sexual function

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Discontinuation & Taper

- Effectively self-tapering: both fluoxetine and norfluoxetine fall gradually at the end of therapy, minimizing discontinuation symptoms.
- The contrast that drives drug choice: Zoloft has a 26-hour half-life and must be reduced gradually. Where adherence is unreliable, fluoxetine is safer.
- A gradual reduction is still preferred; reactions include dysphoric mood, irritability, dizziness, electric shock sensations and insomnia. If they follow a decrease, resume the previous dose.
- Drug holidays are not appropriate; steady state takes 4 to 5 weeks, so a break resets the clock.
- Interactions outlast the drug: for 5 weeks an MAOI and thioridazine stay contraindicated.

Pregnancy & Lactation

- **Pregnancy:** decades of data have not established increased risk of major birth defects or miscarriage.
  - Later exposure may raise the risk of persistent pulmonary hypertension of the newborn; third-trimester exposure has produced respiratory distress, feeding difficulty, hypotonia and irritability.
  - Weigh rather than abstain: women who stopped antidepressants in pregnancy relapsed more often.
- **Lactation:** present in human milk; agitation, irritability, poor feeding and poor weight gain reported.
  - Milk levels run HIGHER than most other SSRIs, relative infant dose roughly 2.4% to 7%, with no adverse developmental effects to 5 years (LactMed 2026).
  - Zoloft is the lower-exposure choice when starting an SSRI while nursing.

- **Exposure Registry:** National Pregnancy Registry for Antidepressants, 1-844-405-6185, womensmentalhealth.org

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Counseling Points

- **Counsel the family on:**
  - Nothing much happening for two weeks. Name the review point aloud: 4 weeks for depression, 5 for OCD.
  - Taking it in the morning, and splitting a dose above 20 mg if nausea is the problem.
  - A missed dose being forgiving here, and a dose increase taking weeks to show for the same reason.
  - Never accepting a 90 mg once-weekly capsule; it has never been studied in children.
  - Telling every future prescriber about fluoxetine taken within the last 5 weeks.
  - Daily home observation for the first month for out-of-character behaviour.
- **Advise them to call for:**
  - New or worsening talk of self-harm, or any abrupt mood change after a dose change.
  - Days without needing sleep, much faster speech, or a jump in energy.
  - Any rash or hives, particularly with fever or joint swelling.
  - Shivering, twitching, stiffness, racing heart, sweating and confusion together.
  - Nosebleeds that will not stop, unexplained bruising, or black stools.
  - Fainting, irregular heartbeat, or a seizure.

References

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