Zoloft

(sertraline)

Zoloft (sertraline); not controlled

Full Prescribing Information	DailyMed Drug Information

Summary

Zoloft is a selective serotonin reuptake inhibitor supplied as a scored tablet and an oral concentrate, with one pediatric indication: obsessive-compulsive disorder from 6 years of age. Response is judged over weeks of continuous dosing. Its short half-life reaches steady state within a week, which is why it titrates fast and why it must be tapered. Not controlled; brand and generic.

Forms & Strengths

- **Tablets, film coated, scored:** 25 mg, 50 mg, 100 mg
- **Oral solution (concentrate, 12% alcohol):** 20 mg/mL
- **Capsules:** 150 mg, 200 mg. Separate label; maintenance only

Dosing

- **Age:**
  - OCD: 6 y/o and older. The only pediatric indication
  - MDD, panic, PTSD, social anxiety: adults only; PMDD: adult women
- **Onset:** 2 to 3 weeks for early effect; 12 weeks for full response in OCD
- **Duration:** continuous with once-daily dosing
- **Initial Dose:**
  - Pediatric OCD, 6 to 12 y/o: 25 mg daily
  - Pediatric OCD, 13 to 17 y/o: 50 mg daily
  - Adults: 50 mg daily; 25 mg for panic, PTSD and social anxiety
- **Titration:**

    - 25 to 50 mg/day increments at intervals of no less than 1 week
    - Therapeutic range 50 to 200 mg/day; halve both in mild hepatic impairment
- **Max Dose:**
    - 200 mg/day at any age from 6 years; 100 mg/day in mild hepatic impairment
    - Moderate or severe hepatic impairment: not recommended
- **Considerations:** Do not initiate or titrate with the 150 mg or 200 mg capsules; their own label forbids it. Screen for bipolar history first; taper when stopping.

Pharmacology

- **Mechanism:** Inhibits serotonin reuptake at SERT with very weak effect on norepinephrine and dopamine, and an unusually clean receptor panel
- **Delivery / Release:** immediate-release tablet or concentrate, approximately bioequivalent; food is no constraint
- **Metabolism:** first-pass N-demethylation to the less active N-desmethylsertraline. Half-life about 26 hours, steady state in one week. Mild hepatic impairment triples exposure
- **Class Positioning:** steady state in a week against fluoxetine's 4 to 5 weeks, so it titrates weekly, at the cost of a discontinuation syndrome Prozac lacks

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Indications

- **Obsessive-Compulsive Disorder** (ICD-10: F42.x): 6 y/o and older. The only pediatric indication
- **Major Depressive Disorder** (ICD-10: F32.x, F33.x): adults only
- **Panic Disorder, PTSD, Social Anxiety Disorder** (ICD-10: F41.0, F43.1, F40.10): adults only
- **Premenstrual Dysphoric Disorder** (ICD-10: N94.3): adult women only

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Off-Label Uses

- **Pediatric anxiety disorders** (ICD-10: F41.1, F40.10, F93.0): sertraline with CBT beat either alone; CBT alone beat sertraline alone for remission (AHRQ 2017). On-label option: Cymbalta from 7 y/o
- **Pediatric major depressive disorder** (ICD-10: F32.x): two trials did not support an indication. Prozac carries that one
- **Pediatric PTSD** (ICD-10: F43.1): insufficient, despite the adult indication
- **Anxiety and irritability in autism** (ICD-10: F84.0): insufficient; a trial in children 24 to 72 months found no difference (Potter 2019)

Contraindications & Warnings

- **Boxed Warning:** SUICIDAL THOUGHTS AND BEHAVIORS in children, adolescents and young adults.
  - Monitor closely for clinical worsening and emergent suicidality in the initial few months and at every dose change, up or down.
  - Counsel family members to watch for behaviour change and alert the prescriber.
- **Contraindicated:**
  - An MAOI concurrently or within 14 days either way, including linezolid and methylene blue, because of serotonin syndrome.
  - Pimozide; and known hypersensitivity, including anaphylaxis and angioedema.
  - ORAL SOLUTION ONLY: concurrent disulfiram, because of its 12% alcohol.
- **Use with caution:**
  - Seizure disorder, unstudied; those patients were excluded from the trials.
  - Untreated narrow angles: the label says AVOID; pupillary dilation can trigger angle closure.
  - QTc risk factors; mild hepatic impairment, halving both dose and ceiling.
  - NSAIDs, aspirin or anticoagulants; diuretics; bipolar disorder or family history.
- **Screen before starting:**
  - Personal or family history of bipolar disorder; the label makes this a numbered dosing step.
  - Baseline height, weight, sexual function and QTc risk; disulfiram if using the solution.

Drug Interactions

- **MAOIs** (selegiline, phenelzine, linezolid, methylene blue): contraindicated. 14 days in both directions, unlike fluoxetine's 5-week exit
- **CYP2D6 substrates, atomoxetine named by the label** (Strattera, propafenone, metoprolol): sertraline raises substrate exposure.
  - Decrease the substrate dose if needed; raise it again once sertraline stops.
  - For atomoxetine, lengthen the titration interval to 4 weeks. 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, TCAs, opioids, lithium, AMPHETAMINES): serotonin syndrome. Stop all for agitation, hyperthermia, rigidity or myoclonus
- **Phenytoin:** check the level when sertraline starts and at each titration step
- **Antiplatelets and anticoagulants** (aspirin, warfarin, NSAIDs): bleeding; monitor the INR
- **QTc-prolonging drugs** (ziprasidone, erythromycin, amiodarone): avoid, or obtain an ECG before each increase

Administration

- Give once daily, morning or evening, with or without food; fix the time and keep it fixed.
- Tablets are scored at every strength, so a 12.5 mg half-step needs no liquid.
- Oral solution: use the SUPPLIED dropper, graduated at 25 mg and 50 mg only. Dilute in 4 ounces of water, ginger ale, lemonade or orange juice ONLY, and drink immediately.
- Do not start or titrate with the 150 mg or 200 mg capsules; their label says do not initiate treatment with them.
- Missed dose: take it the same day; do not double up.
- Switching to or from an MAOI: allow 14 days in either direction.

Side Effects

- **Common:** nausea, insomnia, diarrhea, dry mouth, fatigue, dizziness, somnolence, tremor, agitation, decreased appetite, hyperhidrosis.
  - Pediatric trials add fever, hyperkinesia, urinary incontinence, aggression, epistaxis and purpura.
- **Serious:**
  - Suicidal thoughts and behavior: the boxed warning. Change or stop the regimen if suicidality emerges.
  - Serotonin syndrome: stop every serotonergic agent immediately and treat supportively.
  - Discontinuation syndrome, which on this label explicitly includes SEIZURES. Do not stop abruptly.
  - Mania or hypomania, in 0.4%. Stop and reassess the diagnosis.
  - Hyponatremia and SIADH; QTc prolongation and torsades; bleeding.
  - Weight loss: about 1 kg against placebo; 7% of children aged 6 to 11 lost over 7% of body weight.
  - Angle-closure glaucoma; sexual dysfunction.

Monitoring & Labs

- **Suicidality:** every visit for 3 months, at every dose change either way, then every 3 months. Instruct caregivers to watch for behaviour change at home
- **Activation and mania:** screen for bipolar history before the first dose, then ask about reduced sleep need and pressured speech every 3 months
- **Growth and weight:** plot at baseline, every 3 months for the first year, then every 6 months. Act on a loss over 7%

- **Hyponatremia and bleeding:** check sodium for new headache or confusion; ask about bruising, nosebleeds and purpura every 3 months
- **Urine drug screening:** FALSE-POSITIVE benzodiazepine immunoassays for days after stopping; confirm by mass spectrometry
- **Response:** do not judge OCD efficacy before full titration and 12 weeks; reassess every 6 months, with sexual function

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Discontinuation & Taper

- Sertraline must be tapered; label 2.6 directs gradual reduction, and the 26-hour half-life gives no cushion.
- The contrast that drives drug choice: Prozac is effectively self-tapering. Where a family may run out of a refill, pick fluoxetine.
- Discontinuation reactions include nausea, sweating, dysphoric mood, irritability, dizziness, electric shock sensations, TINNITUS and SEIZURES.
- If intolerable symptoms follow a reduction, return to the previous dose and go slower.
- Drug holidays are not appropriate; a break produces a discontinuation syndrome, not a pause.

Pregnancy & Lactation

- **Pregnancy:** first-trimester studies and meta-analysis show no increase in total or cardiac malformations against background.
  - Later exposure may raise the risk of persistent pulmonary hypertension of the newborn and neonatal respiratory support.
  - Weigh rather than abstain: women who stopped antidepressants relapsed more often.
  - The ORAL SOLUTION contains 12% alcohol and is not recommended in pregnancy.
- **Lactation:** low levels in human milk, with no adverse reactions in a pooled analysis.
  - Relative infant dose about 0.5% to 1%; most authoritative reviewers consider sertraline preferred during breastfeeding (LactMed 2026).
  - Exceptions: neonatal sleep myoclonus, restlessness, diarrhea or agitation, and reduced milk supply (LactMed 2026).
- **Exposure Registry:** National Pregnancy Registry for Antidepressants, 1-866-961-2388, womensmentalhealth.org

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Counseling Points

- **Counsel the family on:**

    - Nothing much happening for two to three weeks; the OCD trial ran 12 weeks.
    - The same time daily, never skipping a weekend; stopping produces withdrawal, not an absent effect.
    - Splitting the scored tablet if the starting dose is too much, rather than skipping days.
    - The liquid: only the supplied dropper, mixed into half a cup of water or juice, drunk straight away.
    - Never accepting a 150 mg or 200 mg capsule while starting or titrating.
    - A urine drug screen reading positive for benzodiazepines for days after stopping.
- **Advise them to call for:**
    - New or worsening talk of self-harm, or an abrupt mood change after a dose change.
    - Days without needing sleep, much faster speech, or a jump in energy.
    - New hitting or aggression, or a child dry at night wetting again.
    - Shivering, twitching, stiffness, racing heart, sweating and confusion together.
    - A seizure, especially after missed doses or an abrupt stop.

References

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