Strattera

(atomoxetine)

Strattera (atomoxetine); not controlled

Full Prescribing Information	DailyMed Drug Information

Summary

Strattera is a selective norepinephrine reuptake inhibitor supplied as an oral capsule, approved for ADHD in adults and in children from 6 years of age. It is dosed on a milligram-per-kilogram basis and gives continuous, all-day coverage rather than a timed stimulant effect, so it is judged over weeks and not over a school day. It is the option to reach for when a stimulant is not tolerated, when tics or anxiety coexist, or when diversion risk makes a controlled substance unattractive. Not controlled; brand and generic.

Forms & Strengths

- **Capsules:** 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg
- **Oral solution (separate NDA, Atoncy):** 4 mg/mL

Dosing

- **Age:** 6 y/o and older, and adults; not established below 6 y/o
- **Onset:** weeks to clinical effect, not minutes; not a rescue or as-needed medication
- **Duration:** continuous with daily dosing; no afternoon wear-off
- **Initial Dose:**
  - Under 70 kg: 0.5 mg/kg/day
  - 70 kg and over, and adults: 40 mg/day
- **Titration:**
  - Under 70 kg: after at least 3 days, to a target of 1.2 mg/kg/day; no added benefit above that

    - 70 kg and over, and adults: after at least 3 days, to 80 mg/day; if response is not optimal after 2 to 4 further weeks, may increase to 100 mg/day
    - CYP2D6 poor metabolizers and patients on a strong CYP2D6 inhibitor: titration interval of 4 weeks, not 3 days. Starting, target and maximum doses unchanged
- **Max Dose:**
    - Under 70 kg: the lesser of 1.4 mg/kg/day or 100 mg/day
    - 70 kg and over, and adults: 100 mg/day
- **Considerations:** Give once daily in the morning, or as two evenly divided doses morning and late afternoon; never more. Reduce to 50% of the usual dose in moderate hepatic impairment and 25% in severe.

Pharmacology

- **Mechanism:** Selective norepinephrine reuptake inhibitor; raises synaptic NE and, indirectly, prefrontal dopamine
- **Delivery / Release:** Immediate-release capsule, no modified-release component; median Tmax 1 hour, but the therapeutic action accrues over weeks.
- **Metabolism:** CYP2D6 to the equipotent 4-hydroxyatomoxetine. Half-life 5.2 hours, 21.6 in poor metabolizers; bioavailability 63%, 94% in poor metabolizers. Protein binding 98%, so dialysis is useless in overdose.
- **Pharmacogenomics:** CYP2D6 poor metabolizers (about 7% White, 2% Asian, 2% Black) have higher exposure and 11% discontinuation against 6%. The action is a 4-week titration interval, not a lower ceiling.
- **Class Positioning:** No striatal DAT blockade, so no euphoriant properties and no schedule; against Concerta the trade-off is weeks-long onset and a smaller effect size. Qelbree titrates in fixed milligram steps, not by weight.

Indications

- **Attention-Deficit/Hyperactivity Disorder** (ICD-10: F90.x): patients 6 y/o and older, and adults, as part of a total treatment program

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Off-Label Uses

- **ADHD with a comorbid tic disorder** (ICD-10: F90.x with F95.2): did not worsen tics in a randomized trial; non-worsening only. Postmarketing reports of new tics exist.
- **ADHD with a comorbid anxiety disorder** (ICD-10: F90.x with F41.x): did not worsen anxiety in randomized trials; supported by controlled trials for non-worsening only.
- **Where the evidence does not support use:**

- **Oppositional defiant disorder** (ICD-10: F91.3) as a target in itself: limited data, and the drug can itself worsen aggression and hostility. [VERIFY: no graded pediatric strength-of-evidence rating located in AHRQ CER 2024]
- **ADHD in autism spectrum disorder** (ICD-10: F84.0 with F90.x): limited data; no atomoxetine-specific grade for this population. (AHRQ 2024)
- **ADHD with substance use disorder** (ICD-10: F90.x with F1x.x): limited data

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Contraindications & Warnings

- **Boxed Warning:** SUICIDAL THOUGHTS AND BEHAVIORS IN PEDIATRIC PATIENTS 6 YEARS OF AGE AND OLDER
  - 0.4% (5 of 1,357) against 0% (0 of 851) on placebo; no suicides
  - Every event occurred in patients 6 to 12 and within the first month
  - Monitor closely at start and at every dose change
- **Contraindicated:**
  - Hypersensitivity; anaphylaxis, angioedema, urticaria and rash reported
  - MAOI use, or within 14 days of stopping one
  - Narrow angle glaucoma; increased risk of mydriasis
  - Pheochromocytoma or a history of it
  - Severe cardiac or vascular disease that would deteriorate with a rise of 15 to 20 mm Hg or 20 bpm
- **Use with caution:**
  - Structural cardiac abnormality, cardiomyopathy or serious arrhythmia; generally should not be used, sudden death reported
  - Hypertension, tachycardia, cerebrovascular disease, or predisposition to hypotension
  - Bipolar disorder or risk factors; can precipitate mania
  - Existing aggression or hostility, which the drug can worsen
  - Moderate or severe hepatic impairment; exposure rises two- and four-fold, so reduce the dose
  - Urinary retention or hesitancy, and any history of priapism
- **Screen before starting:**
  - Personal and family history of bipolar disorder, mania or hypomania
  - Cardiovascular history and exam; ECG or echocardiogram only if either suggests cardiac disease
  - Heart rate, blood pressure, height and weight on a growth chart
  - Routine liver function tests are **not** recommended before or during treatment

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Drug Interactions

- **MAOIs** (phenelzine, tranylcypromine, linezolid, IV methylene blue): risk of a fatal hyperthermic reaction; contraindicated. Allow 14 days in either direction

- **Strong CYP2D6 inhibitors** (fluoxetine, paroxetine, quinidine, bupropion): exposure rises. Do not lower the target dose; lengthen the titration interval to 4 weeks
- **Antihypertensives and pressor agents** (dopamine, dobutamine): blood pressure moves against intent; check it more often and adjust the atomoxetine dose
- **Systemic beta-2 agonists** (oral albuterol): potentiated rise in heart rate and blood pressure; check both more often

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Administration

- Once daily in the morning, or two evenly divided doses morning and late afternoon; no additional doses
- With or without food; food lowers Cmax 37% and delays Tmax about 3 hours, blunting early nausea
- **Swallow the capsule whole. Do not open it;** the contents are an ocular irritant
- Splitting the dose is the usual answer to somnolence or nausea, not a dose reduction
- For a child who cannot swallow capsules, the Atoncy oral solution is the route, under its own label
- **Missed dose:** take it as soon as possible, never exceeding the daily total in 24 hours
- No taper is required when stopping

Side Effects

- **Common** (pediatric acute trials vs placebo):
  - Headache 19 vs 15%, abdominal pain 18 vs 10%, decreased appetite 16 vs 4%
  - Somnolence 11 vs 4%, vomiting 11 vs 6%, nausea 10 vs 5%, fatigue 8 vs 3%
  - Irritability 6 vs 3%, dizziness 5 vs 2%, decreased weight 3 vs 0%
- **Serious:**
  - Suicidal thoughts and behavior, the boxed warning
  - Severe liver injury including failure requiring transplant; stop permanently and do not rechallenge
  - Sudden death with structural cardiac abnormality; stop and evaluate for exertional chest pain or syncope
  - Rise in blood pressure and heart rate; recheck after every dose increase
  - New psychotic or manic symptoms without prior history; consider discontinuing
  - Emergence or worsening of aggression or hostility; consider a drug cause
  - Priapism, an erection over 4 hours; ask adolescent males directly
  - Urinary retention or hesitancy
  - Growth lag over the first 9 to 12 months, then recovery; at 3 years, weight +0.5 kg and height -0.4 cm against prediction, pre-pubertal starters -2.1 kg and -1.2 cm

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Monitoring & Labs

- **Cardiovascular:** heart rate and blood pressure at baseline, after every dose increase, then every 3 months; act on a rise of 15 to 20 mm Hg or 20 bpm. Poor metabolizers rose 9.4 vs 5 bpm
- **Suicidality:** screen at every visit for 3 months and at every dose change, then each routine visit
- **Growth:** height and weight at baseline, every 3 months for a year, then every 6 months; investigate a sustained drop over one major percentile line
- **Liver:** routine testing is **not** recommended
  - Obtain ALT, AST, bilirubin and INR at the **first** sign: pruritus, dark urine, jaundice, right upper quadrant tenderness, unexplained flu-like symptoms
  - Discontinue permanently for jaundice, laboratory evidence of injury, or aminotransferases above 5x the upper limit of normal. (LiverTox 2020)
- **Psychiatric:** ask about new aggression, agitation and manic or psychotic symptoms at each titration visit and every 3 months
- **Genitourinary:** ask about urinary hesitancy each visit and prolonged erection in males every 6 months

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Discontinuation & Taper

- **No taper is needed** (label 2.8); section 9.3 records no symptom rebound and no discontinuation or withdrawal syndrome
- Discontinue permanently and do not restart in any patient with jaundice or laboratory evidence of liver injury
- **Drug holidays are not appropriate.** The effect accrues over weeks of continuous exposure, so a break resets the clock rather than pausing a daily effect
- Reevaluate the continued need for treatment periodically and document indication and response

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Pregnancy & Lactation

- **Pregnancy:** human data insufficient to establish a drug-associated risk. Animal findings include decreased live fetuses and skeletal variants at 3 to 5 times human exposure. Weigh treatment against untreated ADHD.
- **Lactation:** no human milk data in the label; published mean milk concentration 12 mcg/L at 80 mg daily, relative infant dose 0.19%, worst case 0.65%. Two infants slept longer than usual. Monitor for sedation. (LactMed 2026)
- **Exposure Registry:** National Pregnancy Registry for ADHD Medications, 1-866-961-2388, womensmentalhealth.org/adhd-medications

Counseling Points

- **Counsel the family on:**
  - Nothing happening in the first week, with the review point set at 4 to 6 weeks at target dose
  - Giving it every day including weekends and holidays; the effect depends on continuous exposure
  - Swallowing the capsule whole and never opening it; the powder irritates the eyes
  - Moving the second dose later, or taking it with food, for nausea or sleepiness
  - Watching daily for new agitation or unusual behaviour in the first month
  - Stopping without a taper being safe, so there is no need to ration a dwindling supply
- **Advise them to call for:**
  - New talk of self-harm, or any sudden mood or behaviour change, especially early
  - Yellow skin or eyes, dark urine, right-sided rib pain, itching, or flu-like illness; same-day call
  - Chest pain on exertion, fainting, or a racing heartbeat
  - New aggression, hostility, or behaviour out of character
  - An erection lasting more than 4 hours, painful or not, which is an emergency
  - Difficulty starting to urinate, or inability to urinate

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