Focalin

(dexmethylphenidate)

Focalin (dexmethylphenidate hydrochloride); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Focalin is a short-acting, immediate-release tablet of dexmethylphenidate, the d-threo enantiomer of racemic methylphenidate and the more pharmacologically active one, approved for ADHD from age 6. Because the active enantiomer is given alone, the labelled conversion from racemic methylphenidate is half the total daily dose, which is the number most often got wrong when switching. It is the methylphenidate to reach for when a discrete window of coverage is wanted. Schedule II; brand and generic.

Forms & Strengths

- Tablets: 2.5 mg, 5 mg, 10 mg

Dosing

- **Age:**
  - 6-17 y/o: established in two controlled trials
  - Under 6 y/o: not established
  - 18 y/o and older: no adult dose ladder on this label; adult data sit on the Focalin XR label
- **Onset:** ~ 30 min
- **Duration:** 5 to 6 hours
- **Initial Dose:**
  - New to methylphenidate: 5 mg daily, given as 2.5 mg twice daily
  - Currently on racemic methylphenidate: half the current total daily dose

- **Titration:** 2.5 mg to 5 mg every 7 days
- **Max Dose:** 20 mg/day, given as 10 mg twice daily
- **Considerations:** Give twice daily at least 4 hours apart, with or without food. Converting from racemic methylphenidate is half the total daily dose, never milligram for milligram.

Pharmacology

- **Mechanism:** Blocks presynaptic dopamine and norepinephrine reuptake at DAT and NET; does not meaningfully promote catecholamine release at therapeutic doses
- **Delivery / Release:** Plain immediate-release tablet; peak at 1 to 1.5 hours fasted, no accumulation on BID dosing. A high-fat breakfast leaves exposure unchanged but delays the peak to 2.9 hours.
- **Metabolism:** De-esterified to d-ritalinic acid, little or no activity. Not a clinically relevant CYP substrate. Bioavailability 22% to 25%; half-life ~2.2 hours; ~90% urinary.
- **Class Positioning:** The isolated d-threo enantiomer, the more active one, with little interconversion back to the l-isomer. Racemic methylphenidate at twice the milligram amount gives comparable plasma levels, which is the conversion rule.

Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6 y/o and older

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Off-Label Uses

- **Narcolepsy** (ICD-10: G47.419): racemic methylphenidate carries the indication; this enantiomer does not. Insufficient.
- **ADHD in a child aged 4 to 5** (ICD-10: F90.x): behavioral parent training first, methylphenidate only if impairment stays moderate to severe (AAP 2019). That covers racemic methylphenidate; this product is unstudied below 6. Insufficient.
- **Where the evidence does not support use.** AHRQ 2024 grades head-to-head comparisons between stimulants as low strength of evidence, so nothing supports choosing dexmethylphenidate over another agent in an individual child, and nothing supports use outside ADHD in youth.
- **Cognitive enhancement without ADHD:** not an indication and not supported.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction. High potential for abuse and misuse, leading to substance use disorder, overdose and death. Assess risk before prescribing and monitor throughout.
- **Contraindicated:**
  - Hypersensitivity to methylphenidate or any component; angioedema and anaphylaxis reported.
  - Concomitant MAOI, or within 14 days of stopping one; hypertensive crisis.
- **Use with caution:**
  - Structural cardiac abnormality, cardiomyopathy, serious arrhythmia or coronary disease; the label says avoid, because of sudden death reports.
  - Pre-existing hypertension; expect a rise of 2 to 4 mmHg and 3 to 6 bpm, and some patients rise further.
  - Pre-existing psychosis or bipolar disorder; new psychotic or manic symptoms in ~0.1% of stimulant-treated patients.
  - Motor or verbal tics, and Tourette's syndrome.
  - Open-angle glaucoma, raised intraocular pressure, or significant hyperopia.
  - Peripheral vasculopathy including Raynaud's phenomenon.
  - Substance use disorder in patient or household.
- **Screen before starting:**
  - Cardiac disease by history, family history of sudden death or arrhythmia, and exam. No routine ECG.
  - Personal and family history of tics or Tourette's syndrome.
  - Risk factors for mania: past depression, family history of suicide or bipolar disorder.
  - Abuse and diversion risk; baseline height, weight, blood pressure and heart rate.

Drug Interactions

- **MAOIs** (phenelzine, tranylcypromine, selegiline, linezolid, methylene blue): hypertensive crisis. Do not co-prescribe; allow 14 days after stopping.
- **Antihypertensives** (any class): effectiveness may fall. Monitor blood pressure and adjust their dose.
- **Halogenated anesthetics** (sevoflurane, isoflurane, desflurane): sudden intraoperative pressure and rate rise. Avoid on the day of surgery.
- **Risperidone:** a dose change either way may raise EPS risk. Monitor for EPS across any change.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans): serotonin syndrome appears postmarketing, not in the interaction table. Counsel and reassess when adding one.

Administration

- Twice daily, at least 4 hours apart; the first dose usually on waking.

- With or without food. A high-fat breakfast does not change exposure but delays the peak by about 1.4 hours.
- Avoid late-afternoon dosing, which costs sleep.
- **Switching from racemic methylphenidate:** half the current total daily dose. To Focalin XR: the same total daily dose.
- Stop the drug if a month of dose adjustment brings no improvement.
- Store securely, preferably locked. No liquid, chewable or transdermal dexmethylphenidate exists; a child who cannot swallow needs Focalin XR sprinkled or another molecule.

Side Effects

- **Common** (two pediatric placebo-controlled trials): abdominal pain 15% vs 6%, nausea 9% vs 1%, anorexia 6% vs 1%, fever 5% vs 1%. The label adds decreased appetite, insomnia, anxiety, headache, dizziness and tachycardia. 7.3% discontinued for an adverse reaction.
- **Serious:**
  - Sudden death with structural cardiac disease; avoid use, and evaluate exertional syncope promptly.
  - New psychosis or mania, including with no psychiatric history; consider discontinuing.
  - Priapism, sometimes requiring surgery, including during drug holidays. Immediate care.
  - Peripheral vasculopathy including Raynaud's, with digital ulceration; reduce dose or stop.
  - Long-term growth suppression; interrupt if a child is not growing or gaining as expected.
  - Acute angle closure glaucoma and raised intraocular pressure.
  - Angioedema and anaphylaxis; rare rhabdomyolysis and severe hepatic injury postmarketing.

Monitoring & Labs

- **Cardiovascular:** blood pressure and heart rate at baseline, at every dose change, and at least every 6 months. A rise beyond the expected 2 to 4 mmHg, or any symptomatic rise, triggers dose reduction.
- **Growth:** height, weight and BMI at baseline and every 6 months. Crossing two major percentile lines triggers a treatment interruption.
- **Appetite and sleep:** at every visit and dose change. The fix is usually the timing of the second dose, not a dose reduction.
- **Psychiatric and tics:** screen for new psychosis, mania, aggression and emergent tics at every visit.
- **Digits:** inspect fingers and toes for colour change, coldness or ulceration at every visit.

- **Abuse and diversion:** at every refill reassess risk, reconcile the pill count, and check the state PDMP per state requirement. A twice-daily IR product is the easiest methylphenidate to divert.
- **Laboratory:** no routine laboratory monitoring is required.

Discontinuation & Taper

- May be stopped abruptly at therapeutic doses; this label gives no taper instruction.
- After prolonged use expect withdrawal: dysphoria, fatigue, vivid dreams, sleep change, increased appetite, agitation. Strongest in the first days.
- Priapism has occurred during withdrawal and planned holidays; mention it before a holiday in an adolescent male.
- Drug holidays are easy on a twice-daily IR product and reasonable where appetite or growth limits treatment.

Pregnancy & Lactation

- **Pregnancy:** Published studies and postmarketing reports have not identified a drug-associated risk. Stimulants reduce placental perfusion. Delayed fetal ossification in rats at 5 times the maximum human dose; spina bifida in rabbits at 200 mg/kg/day.
- **Lactation:** Present in milk; infant doses were 0.16% to 0.7% of the maternal weight-adjusted dose, with no reported infant effects. Monitor for agitation, insomnia, poor feeding and low weight gain.
- **Dexmethylphenidate specifically:** no clinical use data in lactation; a maternal requirement is not a reason to stop breastfeeding. (LactMed 2025)
- **Exposure Registry:** National Pregnancy Registry for ADHD Medications, 1-866-961-2388, https://womensmentalhealth.org/adhd-medications/

Counseling Points

- **Counsel the family on:**
  - The two-dose structure: the school-day plan must name who gives the midday dose and where it is stored. If none can be arranged, switch to a once-daily product.
  - That the milligram number is deliberately half what a racemic methylphenidate bottle showed, and is not a dose reduction. Pharmacies have read the halving as an error.
  - Rebound irritability and hunger as a dose wears off, which is the drug leaving, not a reason to increase it.

    - Appetite suppression peaking mid-day: move the largest meal to breakfast and to the evening, when appetite returns.
    - Locked storage, and that sharing a Schedule II medication is a felony.
    - Bringing a teacher rating scale to the next visit rather than a verbal impression.
- **Advise them to call for:**
    - Chest pain, fainting, or a racing heart that does not settle.
    - New hallucinations, or new suspicious, fearful or grandiose thinking.
    - Numbness or colour change in the fingers or toes, or a sore that will not heal on a fingertip.
    - A new tic, or a marked worsening of an existing one.
    - Weight loss, or clothes fitting more loosely over a few weeks.
    - A painful erection lasting more than a few hours, including during a planned break.
    - Eye pain, blurred vision, or haloes around lights.

References

1. DailyMed. Focalin (dexmethylphenidate hydrochloride) tablets prescribing information. Novartis. 2023. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7c552f11-e24a-4d9b-bb8d-be10c928eca8
2. DailyMed. Focalin XR (dexmethylphenidate hydrochloride) extended-release capsules prescribing information. Novartis. 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1a1da905-42a0-4748-9c39-67eca45deccc
3. LactMed. Dexmethylphenidate. Drugs and Lactation Database, NICHD. 2025. https://www.ncbi.nlm.nih.gov/books/NBK500764/
4. FDA. National Drug Code Directory, openFDA. Queried by generic name dexmethylphenidate. 2026. https://api.fda.gov/drug/ndc.json
5. American Academy of Pediatrics. Clinical practice guideline for the diagnosis, evaluation, and treatment of ADHD in children and adolescents. Pediatrics. 2019. https://publications.aap.org/pediatrics/article/144/4/e20192528/81590/
6. AHRQ. ADHD diagnosis and treatment in children and adolescents. Comparative Effectiveness Review No. 267. 2024. https://www.ncbi.nlm.nih.gov/books/NBK603001/

Revision #27
Created 2024-12-21 13:51:56 UTC by Josh LeJeune NP
Updated 2026-08-20 06:36:38 UTC by Josh LeJeune NP