

Focalin XR

(dexamethylphenidate XR)

[Full Prescribing Information](#)

[DailyMed Drug Information](#)

Forms/Strengths

- **Capsules:** 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg

Dosing

- **Age:** ≥ 6 y/o
- **Onset:** ~ 30 min
- **Duration:** 8-12 hours
- **Release Profile:** 50% IR, 50% ER
- **Considerations:** Capsules may be swallowed whole or opened, and the entire contents can be sprinkled on applesauce.
- **Initial Dose:**
 - **New to methylphenidate:**
 - 6-17 y/o: 5 mg
 - Adults: 10 mg
 - **Currently on methylphenidate:** Focalin XR dosage is half (1/2) the current total daily dosage of methylphenidate
 - **Currently on Focalin IR:** Give the same daily dose of Focalin XR
- **Titration:**
 - 6-17 y/o: 5 mg weekly
 - Adults: 10 mg weekly
- **Max Dose:**
 - 6-17 y/o: 30 mg/day
 - Adults: 40 mg/day

Quick Facts

- Inhibits dopamine/norepinephrine reuptake; enhances focus, attention, and impulse control
 - Extended-release formulation provides sustained symptom control
 - Uses SODAS technology for a bi-modal release profile (initial and extended release)
 - Contains isolated active dextroisomer (dexmethylphenidate), potentially allowing for lower dosing
 - Common side effects: decreased appetite, insomnia, headache, stomach upset
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Indications

- **ADHD** (ICD-10: F90.0)
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Off-Label Uses

- N/A
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How to Take

- Take **once daily in the morning** to minimize the risk of insomnia.
 - Can be taken **with or without food**; high-fat meals may delay absorption.
 - Swallow the **capsule whole**; do not crush or chew.
 - If needed, the **capsule can be opened, and contents sprinkled on applesauce**—consume immediately without chewing.
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Side Effects

- Common: Dry mouth, dyspepsia, headache, anxiety, decreased appetite
 - Serious: Cardiac issues, psychiatric symptoms, priapism, peripheral vasculopathy, growth suppression in children
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Monitoring / Labs

- **Cardiovascular:** Baseline and routine monitoring of heart rate and blood pressure.
- **Growth in Pediatrics:** Regular monitoring of height and weight to detect growth suppression.

- **Psychiatric Symptoms:** Observe for mood changes, anxiety, or psychosis.
 - **Abuse Potential:** Monitor for misuse or diversion.
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Education

- **When to Call the Doctor:**
 - Severe **mood changes, aggression, or suicidal thoughts**.
 - Chest pain, rapid heartbeat, shortness of breath (**cardiovascular concerns**).
 - Uncontrolled movements, tics, or worsening anxiety.
 - Numbness, coldness, or color changes in fingers or toes (**circulatory issues**).
 - Unexplained weight loss or **delayed growth in pediatric patients**.
 - **Safety Tips:**
 - **Monitor blood pressure and heart rate**, especially in patients with cardiovascular risk.
 - Use caution in patients with **anxiety, bipolar disorder, or psychosis**, as symptoms may worsen.
 - Avoid **caffeine and other stimulants**, which may amplify side effects.
 - Ensure **adequate hydration and nutrition**, as appetite suppression is common.
 - **Tapering may be required** if discontinuing after long-term use.
 - **Parent Tips for Pediatric Patients:**
 - **Encourage a nutrient-dense diet** to counteract appetite suppression.
 - Administer in the **morning before school** for optimal effect.
 - Monitor **school performance and behavioral changes**.
 - Observe for **sleep disturbances**; adjust timing if necessary.
 - Communicate regularly with **teachers and caregivers** about medication effects.
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Additional Information

- **Contraindications:**
 - **Hypersensitivity** to dexamethylphenidate or formulation components.
 - **Use within 14 days of MAOI therapy** (risk of hypertensive crisis).
 - Symptomatic **cardiovascular disease, moderate-to-severe hypertension, hyperthyroidism, glaucoma**.
 - **History of substance use disorder**, unless benefits outweigh risks.
- **Pregnancy:**
 - **Category C**; use only if benefits outweigh risks.
 - May cause **neonatal withdrawal symptoms** or **low birth weight**.
- **Lactation:**
 - **Excreted in breast milk; not recommended** due to potential infant exposure.
- **Drug Interactions:**
 - **Serotonergic drugs** (e.g., SSRIs, SNRIs, MAOIs) increase **serotonin syndrome risk**.

- **Acidifying agents** (e.g., ascorbic acid) may reduce drug absorption.
 - **Alkalinizing agents** (e.g., sodium bicarbonate) may increase dexamethylphenidate levels.
 - May potentiate **hypertensive effects** of certain medications (e.g., decongestants, beta-agonists).
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Revision #25

Created 21 December 2024 13:52:12 by Josh LeJeune NP

Updated 18 February 2025 03:05:47 by Josh LeJeune NP