Concerta

(methylphenidate hydrochloride extended-release, OROS)

Concerta (methylphenidate hydrochloride extended-release, OROS); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Concerta is a long-acting methylphenidate tablet using an OROS osmotic pump to deliver an immediate overcoat dose followed by ascending release from the core, approved for ADHD from age 6 through 65. It is the reference long-acting methylphenidate and the one with a labeled conversion table from immediate-release dosing. Its differentiator is that ascending profile: levels rise across the day rather than plateauing. Schedule II; brand and generic.

Forms & Strengths

- Extended-release tablets (OROS, swallow whole): 18 mg, 27 mg, 36 mg, 54 mg, 72 mg

Dosing

- **Age:** 6 to 65 y/o
- **Onset:** ~ 1 hour
- **Duration:** up to 12 hours
- **Release Profile:** 22% IR / 78% ER via OROS osmotic delivery
- **Initial Dose:**
  - 6 to 17 y/o, new to methylphenidate: 18 mg once daily in the morning
  - 18 to 65 y/o, new to methylphenidate: 18 mg or 36 mg once daily

    - From IR methylphenidate, per dose given 2-3 times daily: 5 mg to 18 mg; 10 mg to 36 mg; 15 mg to 54 mg; 20 mg to 72 mg (13 y/o and older only)
- **Titration:** 18 mg every 7 days; use 27 mg for a smaller step
- **Max Dose:**
    - 6 to 12 y/o: 54 mg/day
    - 13 to 17 y/o: 72 mg/day, not to exceed 2 mg/kg/day
    - 18 to 65 y/o: 72 mg/day
- **Considerations:** Swallow whole; splitting or chewing destroys the extended release. The nondeformable tablet is unsuitable in severe GI narrowing, and the empty shell passing in stool is not a failed dose.

Pharmacology

- **Mechanism:** Blocks presynaptic dopamine and norepinephrine reuptake at DAT and NET; does not meaningfully promote catecholamine release at therapeutic doses
- **Delivery / Release:** 22% IR / 78% ER via OROS osmotic delivery. An overcoat dissolves within an hour, then a push layer forces drug through a laser-drilled orifice; two core layers make release ascending.
- **Metabolism:** De-esterified to PPAA (ritalinic acid), inactive. Not a CYP substrate. Half-life ~3.5 hours, ~90% recovered in urine, no accumulation.
- **Class Positioning:** Ascending, not two-peaked, so no interpeak trough unlike Ritalin LA or Metadate CD. Relexxii is a different OROS product (18% IR overcoat, Tmax 5.5 h), not interchangeable.
- **Alcohol:** no increased release in vitro up to 40%, unlike Metadate CD, which dose-dumps.

Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6 to 65 y/o

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Off-Label Uses

- **ADHD in children 4 to 5 years old** (ICD-10: F90.x): behavioral parent training first line; if medication is needed use IR methylphenidate, not OROS. Expert consensus. (AAP 2019)
- **Narcolepsy** (ICD-10: G47.419): IR methylphenidate carries this indication, Concerta does not. Insufficient.
- **Where the evidence does not support use:** treatment-resistant depression, binge eating disorder, cancer-related and chronic fatigue. Adult literature only; insufficient in children. (AHRQ 2024)

- **Cognitive enhancement in a youth without ADHD:** not an indication and not supported.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse and addiction, with overdose and death; risk rises with dose and with non-oral routes. Assess abuse risk before prescribing and reassess throughout treatment.
- **Contraindicated:**
  - Hypersensitivity to methylphenidate; angioedema and anaphylaxis reported
  - MAOI use, current or within 14 days: hypertensive crisis
- **Use with caution:**
  - Structural cardiac abnormality, cardiomyopathy, arrhythmia or coronary disease: avoid
  - Pre-existing hypertension: mean rises 2 to 4 mm Hg and 3 to 6 bpm
  - Psychotic or bipolar disorder: exacerbation and treatment-emergent mania
  - Severe GI narrowing: obstruction reported with nondeformable tablets
  - Significant hyperopia or angle-closure risk: refer to ophthalmology
  - Personal or family history of tics or Tourette's syndrome
  - Substance use disorder in the patient or the household
- **Screen before starting:**
  - Cardiac history and exam including family sudden death; the label requires no routine ECG
  - Tics, and mania risk factors: depressive symptoms, family history of bipolar disorder
  - Abuse and diversion risk in patient and household
  - Ability to swallow a tablet whole; any GI stricture or bowel surgery
  - Baseline height, weight, blood pressure and heart rate

Drug Interactions

- **MAOIs** (phenelzine, tranylcypromine, selegiline, linezolid, methylene blue): hypertensive crisis. Contraindicated within 14 days.
- **Antihypertensives:** effectiveness reduced. Increase BP monitoring and adjust the antihypertensive.
- **Halogenated anesthetics** (sevoflurane, isoflurane, desflurane): intraoperative BP and HR surge. Hold on the day of surgery.
- **Risperidone:** EPS may increase when either dose changes in either direction. Monitor across any titration.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, tramadol): serotonin syndrome in postmarketing reports only, not in the interaction table. Counsel on symptoms rather than avoiding.

Administration

- Once daily in the morning, with or without food; a high-fat breakfast changes nothing.
- Swallow whole. Splitting, crushing or chewing destroys the extended release.
- No sprinkle option. If the child cannot swallow a tablet, use a bead capsule or a liquid (Quillivant XR).
- The intact shell is often visible in stool; it is the spent pump, not a lost dose.
- Never substitute milligram-for-milligram; use the labeled conversion table.
- Missed dose: skip it; a mid-afternoon OROS dose costs that night's sleep.
- Store locked; household diversion of a Schedule II product is a real risk.

Side Effects

- **Common, pediatric 6 to 17 y** (>= 2%): upper abdominal pain 6%, insomnia 3%, nasopharyngitis 3%, vomiting 3%, pyrexia 2%.
- **Common, adults:** decreased appetite 25%, headache 22%, dry mouth 14%, nausea 13%, insomnia 12%, anxiety 8%, weight loss 7%, dizziness 7%, irritability 6%, tachycardia 5%.
- **Serious:**
  - Sudden death with structural cardiac disease: avoid the drug rather than monitor through it
  - New psychosis or mania, ~0.1% in pooled trials versus 0% on placebo: consider discontinuing
  - Priapism, sometimes surgical, typically after a dose increase and also during drug holidays
  - Peripheral vasculopathy and Raynaud's with digital ulceration: assess digits at each visit
  - Growth suppression: about 2 cm and 2.7 kg less over 3 years; GI obstruction in pre-existing narrowing
  - Acute angle closure glaucoma; new or worsening tics and Tourette's: discontinue if appropriate
  - Postmarketing: convulsion, hepatocellular injury, rhabdomyolysis, pancytopenia, angioedema, anaphylaxis

Monitoring & Labs

- **Cardiovascular:** BP and HR at baseline, at every dose change, and at least every 6 months. Investigate a sustained rise beyond 2 to 4 mm Hg or 3 to 6 bpm.

- **Growth:** height, weight and BMI at baseline and every 6 months, every visit if losing weight. Crossing two percentile channels triggers interruption.
- **Appetite and sleep:** at every visit and dose change; appetite suppression is worst at midday.
- **Psychiatric and tics:** screen for psychosis, mania, aggression, depressed mood and tics at baseline and every visit.
- **Abuse and diversion:** at every refill, pill count, ask about sharing and selling, check the PDMP. A boxed-warning obligation.
- Where diversion risk decides, neither non-stimulant (Strattera, Qelbree) is a controlled substance.
- **Gastrointestinal:** ask about obstructive symptoms each visit where there is a stricture history. No routine labs; CBC and chemistry are not label-directed.

Discontinuation & Taper

- No taper required; the label gives no tapering schedule.
- Discontinue if no improvement after appropriate dose adjustment over one month.
- Withdrawal after prolonged use: dysphoria, fatigue, vivid dreams, sleep change, increased appetite.
- Priapism has occurred during drug holidays; mention it when planning one.
- Drug holidays are reasonable where growth or appetite limits treatment; an interrupted day is fully unmedicated.

Pregnancy & Lactation

- **Pregnancy:** human data are inconsistent on major birth defects and miscarriage. Stimulant vasoconstriction may reduce placental perfusion. Background risk 2% to 4% and 15% to 20%. Weigh against untreated maternal ADHD.
- **Lactation:** infant dose 0.16% to 0.7% of the maternal weight-adjusted dose; undetectable in infant serum in every reported case, including Concerta 36 mg. Not a reason to stop breastfeeding. (LactMed 2025)
- **Lactation, milk supply:** prolactin falls; large doses may interfere before supply is established. Monitor the infant for agitation, insomnia and poor weight gain. (LactMed 2025)
- **Exposure Registry:** National Pregnancy Registry for ADHD Medications, 1-866-961-2388, womensmentalhealth.org/adhd-medications.

Counseling Points

- **Counsel the family on:**
  - Seeing the intact shell in the stool. Say it before the first dose, or families stop the drug.
  - Half an 18 mg tablet is not 9 mg, it is a broken pump. The 27 mg strength exists to avoid cutting.
  - The ascending release: effect builds through the day; the hardest hours are the first and the last.
  - Moving the largest meal to breakfast and the evening. Upper abdominal pain, the only pediatric reaction above 5%, usually settles.
  - Locked storage; sharing or selling a Schedule II medication is a felony, and adolescents are the ones being asked.
- **Advise them to call for:**
  - Chest pain, fainting, or a racing heart that does not settle.
  - New hallucinations, or suspicious or fearful thinking; eye pain with halos around lights.
  - Numbness, coldness or colour change in fingers or toes, or a sore that will not heal.
  - A new or markedly worse tic, including throat clearing and blinking.
  - A painful erection lasting more than a few hours, including during a planned break.
  - Severe abdominal pain, vomiting or constipation, especially with bowel narrowing.
  - Clothes fitting more loosely, or no weight gain across a few months.

References

1. DailyMed. Concerta (methylphenidate hydrochloride) extended-release tablets prescribing information. Janssen Pharmaceuticals. 2026. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1a88218c-5b18-4220-8f56-526de1a276cd
2. FDA. openFDA National Drug Code Directory, generic_name methylphenidate. 2026. https://api.fda.gov/drug/ndc.json?search=generic_name:%22methylphenidate%22&limit=1000
3. LactMed. Methylphenidate. Drugs and Lactation Database, NICHD. 2025. https://www.ncbi.nlm.nih.gov/books/NBK501310/
4. 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/
5. AHRQ. Attention deficit hyperactivity disorder: diagnosis and treatment in children and adolescents. Comparative Effectiveness Review No. 267. 2024. https://www.ncbi.nlm.nih.gov/books/NBK602989/

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