Metadate CD

(methylphenidate hydrochloride extended-release, biphasic beads)

Metadate CD (methylphenidate hydrochloride extended-release, biphasic beads); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Metadate CD is a bead-filled methylphenidate capsule delivering 30% of the dose immediately and holding 70% in extended-release beads, approved for ADHD in children 6 to 15 years. Weighting the dose toward the afternoon is its differentiator: less morning spike and more late coverage than the 50 / 50 bead capsules. The capsule can be opened and sprinkled without changing exposure. Schedule II; brand and generic.

Forms & Strengths

- Extended-release capsules (biphasic beads, may be opened onto applesauce): 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg

Dosing

- **Age:** 6 to 15 y/o only; no indication at 16, 17 or in adults
- **Onset:** ~ 1 hour
- **Duration:** about 8 hours
- **Release Profile:** 30% IR / 70% ER via biphasic beads
- **Initial Dose:** 20 mg once daily in the morning, before breakfast
- **Titration:** 10 - 20 mg every 7 days
- **Max Dose:** 60 mg/day

- **Considerations:** Give before breakfast; a high-fat meal raises Cmax ~30% and delays the peak an hour. Alcohol releases 84% of the dose in the first hour, so counsel adolescents. May be opened onto applesauce.

Pharmacology

- **Mechanism:** Blocks presynaptic dopamine and norepinephrine reuptake at DAT and NET; does not meaningfully promote catecholamine release at therapeutic doses
- **Delivery / Release:** 30% IR / 70% ER via biphasic beads. First peak at a median 1.5 h, second at ~4.5 h; a quarter to a third of children show only one peak.
- **Metabolism:** De-esterified to ritalinic acid, inactive. Not a CYP substrate. Mean terminal half-life 6.8 hours, against 2.9 h for IR tablets and 3.4 h for OROS.
- **Class Positioning:** The most afternoon-weighted bead capsule: 30/70 against the 50/50 of Ritalin LA. Against Concerta it is two-peaked and can be sprinkled. Its liability is alcohol.
- **Alcohol:** at 40% alcohol, 84% of the dose is released within the first hour; Concerta shows no such release. The label instructs counseling to avoid alcohol.

Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6 to 15 y/o

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Off-Label Uses

- **ADHD at 16 and older, including adults** (ICD-10: F90.x): easy to do inadvertently, since a stable 15 year old becomes off-label on a birthday. Insufficient. (AHRQ 2024)
- **ADHD in children 4 to 5 years old** (ICD-10: F90.x): behavioral parent training first line; if medication is needed use IR methylphenidate. Expert consensus. (AAP 2019)
- **Narcolepsy** (ICD-10: G47.419): IR methylphenidate carries this indication, Metadate CD 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. Assess abuse risk before prescribing and reassess throughout treatment.
- **Contraindicated:**
  - Hypersensitivity to methylphenidate or any component
  - MAOI use, current or within 14 days: hypertensive crisis
- **Use with caution:**
  - Structural cardiac abnormality, cardiomyopathy, arrhythmia or coronary disease: avoid
  - Pre-existing hypertension: monitor blood pressure and pulse
  - Psychotic or bipolar disorder: exacerbation and treatment-emergent mania
  - Significant hyperopia or angle-closure risk: refer to ophthalmology
  - Personal or family history of tics or Tourette's syndrome
  - Any adolescent drinking alcohol or at risk of it
  - Substance use disorder in patient or household; a bead capsule is not abuse-deterrent
- **Screen before starting:**
  - Cardiac history and exam including family sudden death; the label requires no routine ECG
  - Tics, and risk factors for a manic episode
  - Alcohol use in an adolescent, asked directly and separately from other substance use
  - Abuse and diversion risk in patient and household
  - Baseline height, weight, blood pressure and heart rate; age against the 6 to 15 indication

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Drug Interactions

- **MAOIs** (phenelzine, tranylcypromine, selegiline, linezolid, methylene blue): hypertensive crisis. Contraindicated within 14 days.
- **Alcohol:** 84% released in the first hour at 40% alcohol. Advise every adolescent to avoid it; pick another agent where drinking is likely.
- **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.

Administration

- Once daily in the morning, before breakfast, which is a labeled instruction.
- Swallow whole, or sprinkle onto about a tablespoon of applesauce and give immediately with fluids.
- Sprinkling does not change Cmax or AUC. Never store the mixture.
- Do not crush or chew; chewing turns the extended fraction into an immediate one.
- Avoid alcohol: at 40% alcohol, 84% of the dose is released in the first hour.
- Missed dose: skip it; a late dose peaks in the evening.
- Store locked; a bead capsule is easily opened.

Side Effects

- **Common, pediatric 6 to 15 y** (>= 5% and above placebo): headache 12% vs 8%, anorexia 9% vs 2%, abdominal pain 7% vs 4%, insomnia 5% vs 2%. Anorexia and insomnia show the widest gap over placebo.
- **Serious:**
  - Cardiac arrest and sudden death with structural cardiac disease: avoid in that population
  - New psychosis or mania, including with no psychiatric history: 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 each visit
  - Long-term growth suppression; acute angle closure glaucoma; new or worsening tics and Tourette's
  - Postmarketing: suicidal behavior including completed suicide, aggression, OCD, thrombocytopenia, angioedema, rhabdomyolysis, convulsions, cerebral hemorrhage

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Monitoring & Labs

- **Alcohol use:** ask at every visit from about age 12. This product releases 84% of the dose within an hour with alcohol.
- **Appetite and weight:** at every visit; ask whether breakfast is actually eaten.
- **Growth:** height, weight and BMI at baseline and every 6 months; failure to gain triggers interruption.
- **Cardiovascular:** BP and HR at baseline, at every dose change, and at least every 6 months.
- **Sleep:** at every visit and dose change; with 70% extended, an evening problem is likelier the drug than the child.
- **Psychiatric and tics:** screen for psychosis, mania, aggression, depressed mood and tics at every visit; ask about suicidal thoughts where depression is comorbid.

- **Age against indication:** check at every annual visit. The indication ends at 15; plan the switch before 16. Concerta is labeled to 65, Aptensio XR has no upper limit.
- **Abuse and diversion:** at every refill, capsule count, ask about sharing and selling, check the PDMP. A boxed-warning obligation.
- **Laboratory:** none is required by this label.

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 and on discontinuation.
- Drug holidays are reasonable where growth limits treatment; a capsule cannot be part-dosed, and the gap is felt most in the afternoon.

Pregnancy & Lactation

- **Pregnancy:** no drug-associated risk of major birth defects or miscarriage identified. Stimulant vasoconstriction may reduce placental perfusion. Background risk 2% to 4% and 15% to 20%.
- **Lactation:** infant dose 0.16% to 0.7% of the maternal weight-adjusted dose; undetectable in infant serum in every reported case. 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:**
  - Alcohol releasing most of the day's dose in an hour. Say it to the adolescent directly, before the first prescription.
  - Giving the capsule before breakfast, not with it; a fatty breakfast raises the peak by a third.
  - About a tablespoon of applesauce, taken at once, never chewed or made up in advance. Exposure matches the intact capsule.

    - The dose being weighted to the afternoon, 30% now and 70% later, so the morning effect is smaller.
    - The approval ending at 15, so the plan changes in mid-adolescence.
    - Locked storage; a capsule of loose beads is easily emptied.
- **Advise them to call for:**
    - Chest pain, fainting, or a racing heart that does not settle.
    - New hallucinations, or new suspicious or fearful thinking.
    - Any talk of self-harm or suicide, or a marked drop in mood.
    - 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.
    - Unusual bruising or bleeding; eye pain with halos around lights.
    - Clothes fitting more loosely, or no weight gain across a few months.

References

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