Ritalin LA

(methylphenidate hydrochloride extended-release, bimodal beads)

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Full Prescribing Information	DailyMed Drug Information

Summary

Ritalin LA is a bead-filled methylphenidate capsule carrying half its dose as immediate-release beads and half as enteric-coated delayed-release beads, reproducing a twice-daily Ritalin regimen in one morning capsule. Its approval is narrower than any other long-acting methylphenidate here: ADHD in children 6 to 12 years only. The capsule can be opened onto applesauce, so it suits a child who cannot swallow. Schedule II; brand and generic.

Forms & Strengths

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

Dosing

- **Age:** 6 to 12 y/o only; no adolescent and no adult indication
- **Onset:** ~ 1 hour
- **Duration:** about 8 hours
- **Release Profile:** 50% IR / 50% DR via bimodal beads
- **Initial Dose:**
  - New to methylphenidate: 20 mg once daily in the morning; 10 mg where a lower start is appropriate

    - From Ritalin twice daily, per dose: 5 mg to 10 mg; 10 mg to 20 mg; 15 mg to 30 mg; 20 mg to 40 mg; 30 mg to 60 mg once daily
- **Titration:** 10 mg every 7 days
- **Max Dose:** 60 mg/day
- **Considerations:** Switching from any methylphenidate other than Ritalin means titrating from the start, not converting milligram-for-milligram. Capsules may be opened onto cool applesauce.

Pharmacology

- **Mechanism:** Blocks presynaptic dopamine and norepinephrine reuptake at DAT and NET; does not meaningfully promote catecholamine release at therapeutic doses
- **Delivery / Release:** 50% IR / 50% DR via bimodal beads. Enteric-coated beads release past gastric pH, giving two peaks about 4 hours apart with less fluctuation than two separate tablets.
- **Metabolism:** De-esterified to ritalinic acid, inactive. Not a CYP substrate. Half-life 2.5 h in children, 3.5 h in adults. No accumulation once daily.
- **Class Positioning:** Two discrete peaks, not an ascending ramp, and a shallower dip than two separate Ritalin tablets. Against Metadate CD the split is 50/50 not 30/70; against Concerta it can be sprinkled but stops at 12.
- **Cardiac electrophysiology:** no QT study on this product; the dexmethylphenidate study cited found mean QTcF under 5 ms.

Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6 to 12 y/o

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Off-Label Uses

- **ADHD in adolescents 13 to 17 and in adults** (ICD-10: F90.x): the commonest off-label use; no adolescent efficacy data. Insufficient for this product. (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, Ritalin LA 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
  - Substance use disorder in patient or household; beads can be crushed, so this 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
  - Abuse and diversion risk in patient and household
  - Baseline height, weight, blood pressure and heart rate
  - Age against the 6 to 12 indication; near 13, pick an agent labeled for adolescents

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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; a common pairing in ADHD with aggression.
- **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; no food timing needed, and no dose dumping.
- Swallow whole, or open onto a spoonful of applesauce that is cool, never warm; heat damages the coating on the delayed beads.
- Swallow the applesauce mixture at once and entirely, without chewing; never prepare it in advance.
- Do not crush, chew or divide the beads; chewing converts the whole dose to immediate release.
- Switching from any methylphenidate other than Ritalin: titrate from the beginning, never milligram-for-milligram.
- Missed dose: skip it; a late dose puts the delayed bead peak in the evening.
- Store locked; an openable bead capsule is straightforward to misuse.

Side Effects

- **Common:** headache, insomnia, upper abdominal pain, decreased appetite, anorexia. No pediatric percentages published.
- **Serious:**
  - Sudden death with structural cardiac disease: avoid the drug 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; the whole indicated population is prepubertal
  - Acute angle closure glaucoma; new or worsening tics and Tourette's
  - Postmarketing: convulsions, choreoathetoid dyskinesia, cerebral vasculitis and hemorrhage, serotonin syndrome

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Monitoring & Labs

- **Growth:** height, weight and BMI at baseline and every 6 months, every visit if losing weight.
- **Cardiovascular:** BP and HR at baseline, at every dose change, and at least every 6 months.
- **Appetite and sleep:** at every visit and dose change; suppression is heaviest at the morning peak.
- **Afternoon coverage:** ask at every visit about the hours after the second peak. Late-afternoon return is expected; change product rather than raise the dose.

- **Age against indication:** check at every annual visit. At 13 this becomes off-label with no adolescent efficacy data; plan the switch first. Concerta is labeled to 65, Aptensio XR has no upper limit.
- **Psychiatric and tics:** screen for psychosis, mania, aggression, depressed mood and tics at baseline and every visit.
- **Abuse and diversion:** at every refill, capsule count, ask about sharing and selling, check the PDMP. A capsule made to be opened is not abuse-deterrent.
- **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.
- Switching to another methylphenidate: titrate the new product from its own starting dose.

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:**
  - The applesauce rule: cool never warm, swallowed at once, never chewed, never made up in advance.

    - The two-peak pattern: a mid-morning lull is not a failed dose.
    - Coverage reaching early afternoon, not evening; if homework is the problem, this is the wrong product.
    - Giving breakfast before the capsule; the morning half is what flattens appetite.
    - Never chewing the beads; chewed beads turn a full-day dose into one immediate-release hit.
    - The 6 to 12 approval, so the plan will change in adolescence. Say it early, or the switch reads as failure.
    - 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 suspicious 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.
    - Any seizure, or a jerking movement the child cannot stop.
    - Clothes fitting more loosely, or no weight gain across a few months.

References

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