Quillivant XR

(methylphenidate hydrochloride)

Quillivant XR (methylphenidate hydrochloride); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Quillivant XR is a long-acting methylphenidate supplied as a banana-flavoured powder the pharmacist reconstitutes into an extended-release oral suspension, dosed from age 6 with no upper limit. Drug is ion-bound to resin held in suspension, giving a full school-day profile as a liquid. It is the only long-acting methylphenidate dosed by the millilitre. Schedule II; brand only.

Forms & Strengths

- Extended-release oral suspension (banana, contains sucrose; reconstituted from powder): 25 mg/5 mL, that is 5 mg/mL

Dosing

- **Age:** >= 6y; no upper limit
- **Onset:** ~ 45 minutes
- **Duration:** up to 12 hours
- **Release Profile:** 20% IR / 80% ER via drug ion-bound to suspended resin
- **Initial Dose:** 20 mg, which is 4 mL, once daily in the morning
- **Titration:** 10 - 20 mg every 7 days
- **Max Dose:** 60 mg/day, which is 12 mL
- **Considerations:** Shake vigorously at least 10 seconds before every dose or the dose drawn will be wrong. The reconstituted suspension is stable 4 months at room temperature.

Pharmacology

- **Mechanism:** Blocks presynaptic dopamine and norepinephrine reuptake at DAT and NET; does not meaningfully promote catecholamine release at therapeutic doses
- **Delivery / Release:** 20% IR / 80% ER. Drug is complexed to resin particles that settle, which is why the bottle must be shaken before every dose. Median Tmax about 4 hours.
- **Metabolism:** De-esterified to ritalinic acid, inactive. No CYP pathway. Terminal half-life ~5.2 h in children, ~5.6 h in adults; ~90% recovered in urine.
- **Class Positioning:** The only full-day methylphenidate that is a true liquid with a continuous dose. Same 12 hours as Cotempla XR-ODT but with millilitre granularity; QuilliChew ER covers 8 hours.

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: G47.411, G47.419): IR methylphenidate carries this indication, Quillivant XR does not. Limited data.
- **ADHD in children under 6 years** (ICD-10: F90.x): **the label records evidence against.** Higher exposure than older children at the same dose, and more adverse reactions including weight loss. (AHRQ 2024)
- **Weight-based or mg/kg dosing:** the ladder is fixed at 20 mg for everyone 6 and above. Insufficient.
- **Enteral feeding tube:** not studied; a resin suspension is a plausible tube-blocking hazard. Insufficient.
- **Adolescents and adults:** the efficacy study enrolled 45 children aged 6 to 12. Limited data.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse and addiction, with overdose and death; risk rises with dose and 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 mmHg and 3 to 6 bpm
  - Psychotic or bipolar disorder: exacerbation and treatment-emergent mania
  - Personal or family history of tics or Tourette's; tic ran 2% against 0% on placebo
  - Significant hyperopia or angle-closure risk: refer to ophthalmology
  - Substance use disorder in patient or household; a sweet liquid is the most accessible presentation here
- **Screen before starting:**
  - Cardiac history and exam, plus family history of sudden death; mandatory in section 2.1
  - Tics or Tourette's, personal and family, with clinical evaluation; also mandatory
  - Whether the caregiver can shake the bottle and draw an accurate volume daily
  - Mania risk factors; abuse and diversion risk in patient and household
  - 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. Counsel on symptoms rather than avoiding.
- **Alcohol:** the label says avoid it; exposure rose about 20% at 20% alcohol, smaller than the bead and chewable products.
- **Gastric pH modulators** (H2-blockers, PPIs): not on this label, though the sibling resin product Cotempla XR-ODT restricts them. Uncharacterised here.

Administration

- **Reconstitution is a pharmacist step:** add the specified water volume, insert the adapter, shake 10 seconds, dispense in the original carton with the dispenser.
- **Shake vigorously at least 10 seconds before every dose;** an unshaken bottle runs weak early and strong late.

- **Beyond-use date 4 months.** Have the pharmacy date the bottle. Store at room temperature, not refrigerated.
- Once daily in the morning. Food does not delay it; a high-fat meal shortens Tmax by about an hour.
- Measure with the supplied dispenser, never a kitchen spoon; milligrams divided by five gives millilitres.
- Missed dose: give the next as scheduled; never double up or dose late in the day.
- Switching from another methylphenidate: re-titrate from 20 mg weekly, never mg-per-mg.
- Store locked; a palatable liquid is the easiest form for an unintended child to swallow.

Side Effects

- **Common, this product** (45 patients, 6 to 12 y): affect lability 9% vs 2%, excoriation 4% vs 0%, and insomnia, tic, decreased appetite, vomiting, rash each 2% vs 0%.
- **Common, pooled methylphenidate:** decreased appetite and weight, nausea, abdominal pain, insomnia, anxiety, irritability, dizziness, tremor, raised BP and heart rate.
- **Serious:**
  - Sudden death with structural cardiac disease: avoid the drug rather than monitor through it
  - New psychosis or mania, ~0.1% pooled, 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
  - Growth suppression: about 2 cm and 2.7 kg less over 3 years
  - Acute angle closure glaucoma; new or worsening tics and Tourette's: discontinue if appropriate
  - Hypersensitivity including angioedema and anaphylaxis
  - Postmarketing: severe hepatocellular injury, serotonin syndrome, seizures, rhabdomyolysis, pancytopenia

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Monitoring & Labs

- **Shaking technique:** at the first follow-up and any unexplained change in effect, have the caregiver show how they shake. Effect drifting across the month is the signature failure.
- **Beyond-use date and dose volume:** check the reconstitution date and the millilitres drawn at every refill and dose change. A misread dispenser is a silent halving or doubling.
- **Affect lability:** ask at every visit. The highest signal in this product's own trial, 9% against 2%.

- **Cardiovascular:** BP and HR at baseline, at each dose change, and every 6 months.
- **Growth:** height, weight and BMI at baseline and every 6 months. Crossing two percentile lines is a labeled trigger to interrupt.
- **Appetite, sleep, psychiatric and tics:** at every visit and after each dose increase; inspect fingers and toes for colour change or ulceration.
- **Abuse and diversion:** reconcile volume remaining against days elapsed at each refill and check the PDMP. A boxed-warning obligation.
- **Laboratory:** none required. Check LFTs only for jaundice, dark urine or unexplained fatigue. Discontinue if no improvement after one month of appropriate adjustment.

Discontinuation & Taper

- Can be stopped abruptly at therapeutic doses; the label gives no taper schedule.
- Withdrawal after prolonged use: dysphoria, fatigue, vivid dreams, sleep change, increased appetite.
- Down-titration is smoother than on any solid: 1 mL, that is 5 mg, steps.
- Reduce or discontinue for paradoxical worsening or adverse reactions.
- Drug holidays are reasonable where growth limits treatment, but a long one outlasts the bottle.
- Priapism has been reported during drug holidays and on discontinuation.

Pregnancy & Lactation

- **Pregnancy:** human data are insufficient to inform a drug-associated risk. 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 plasma in every reported case. Monitor for agitation, poor feeding and reduced weight gain. Not a reason to stop breastfeeding. (LactMed 2025)
- **Lactation, milk supply:** prolactin falls; large doses may interfere before supply is established. (LactMed 2025)
- **Exposure Registry:** National Pregnancy Registry for Psychostimulants, 1-866-961-2388, womensmentalhealth.org.

Counseling Points

- **Counsel the family on:**
  - **Shaking hard for a full 10 seconds before every dose.** Count it out loud with them once; a poorly shaken bottle runs weak then strong across the month.

    - The 4-month limit from the reconstitution date, room-temperature storage, and using only the supplied dispenser: 1 mL is 5 mg.
    - The flavour being banana, so a child who has refused banana medicines will refuse this.
    - Emotional swings being a recognised effect of this product, manageable by dose. Move the largest meal to breakfast and the evening.
    - Locked storage; a toddler can drink a large amount of a sweet liquid quickly.
- **Advise them to call for:**
    - Chest pain, fainting, or a racing heart that does not settle.
    - New hallucinations, or suspicious or fearful thinking.
    - Numbness, coldness or colour change in fingers or toes.
    - A new or markedly worse tic, or a new vocal tic.
    - Weight loss, clothes fitting more loosely, or a marked change in emotional control.
    - A painful erection lasting more than a few hours.
    - Yellowing of the eyes or skin, dark urine, or new eye pain with halos around lights.
    - Any amount swallowed by a child it was not prescribed for.

References

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