Relexxii

(methylphenidate ER [OROS])

Full Prescribing Information	DailyMed Drug Information

> Relexxii is a tablet-shaped version of Concerta, offering the same OROS delivery system and bioequivalence. It also comes in additional dosage strengths.

Forms/Strengths

- **Tablets:** 18 mg, 27 mg, 36 mg, 45 mg, 54 mg, 63 mg, 72 mg

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Dosing

- **Age:** ≥ 6 y/o
- **Onset:** ~60 min
- **Duration:** 8-12 hours
- **Release Profile:** 20% IR, 80% CR via osmotic delivery
- **Considerations:** Must be swallowed whole; the non-absorbable shell may pass in stool. Administer once daily in the morning, with or without food. Do not chew or crush the tablet.
- **Initial Dose:**
  - **6-12 y/o:** 18 mg once daily in the morning
  - **13+ y/o:** 18 mg once daily in the morning
- **Titration:** Increase by 18 mg/day at weekly intervals
- **Max Dose:**
  - **6-12 y/o:** 54 mg/day
  - **13+ y/o:** 72 mg/day
  - **Adults:** 72 mg/day

Quick Facts

- Blocks dopamine/norepinephrine reuptake; improves focus, attention, and impulse control
- Extended-release formulation with a unique multi-phase release for rapid onset and sustained effect
- Once-daily dosing for consistent ADHD symptom management
- Common side effects: decreased appetite, insomnia, headache, gastrointestinal discomfort

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Indications

- **ADHD** (ICD-10: F90.0)

Off-Label Uses

- **N/A**

How to Take

- Take **once daily in the morning** to minimize the risk of insomnia.
- Can be taken **with or without food**.
- **Swallow the tablet whole with liquid**; do not chew, divide, or crush.
- Avoid taking **late in the day** to prevent sleep disturbances.

Side Effects

- Common: Decreased appetite, headache, dry mouth, nausea, insomnia, anxiety, dizziness, weight loss, irritability, increased sweating.
- Pediatric patients: Abdominal pain

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.

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.

Additional Information

- **Contraindications:**
  - **Hypersensitivity** to methylphenidate 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 methylphenidate levels.
- May potentiate **hypertensive effects** of certain medications (e.g., decongestants, beta-agonists).

Revision #16
Created 28 December 2024 04:00:28 by Josh LeJeune NP
Updated 18 February 2025 03:09:44 by Josh LeJeune NP