

# Dyanavel XR

(amphetamine ER)

Full Prescribing Information

DailyMed Drug Information

## Forms/Strengths

- **Tablets:** 5 mg, 10 mg, 15 mg, and 20 mg
- **Liquid:** 2.5 mg/mL (Total Bottle: 464 mL)

## Dosing

- **Age:**  $\geq 6$  y/o
- **Onset:** ~60 min
- **Duration:** up to 13 hours
- **Considerations:** May be taken with or without food. Liquid and tablet formulations are interchangeable.
  - **Tablet:** The 5mg dose is scored to allow for accurate dosing down to 2.5mg.
  - **Liquid:** Bubblegum flavor
- **Initial Dose:**
  - 6-12 y/o: 2.5-5 mg
  - 13+ y/o: 5-10 mg
- **Titration:**
  - 6-12 y/o: 2.5 mg every 4-7 days
  - 13+ y/o: 5 mg every 4-7 days
- **Max Dose:** 20 mg

## Quick Facts

- Increases synaptic dopamine and norepinephrine; improves focus, attention, and impulse control
- Extended-release oral suspension; liquid formulation for ease of administration

- Unique delivery system provides consistent, sustained symptom control
  - Common side effects: decreased appetite, insomnia, increased heart rate, elevated blood pressure
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## Indications

- **ADHD** (ICD-10: F90.0)
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## Off-Label Uses

- N/A
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## How to Take

- Take **once daily in the morning** to reduce the risk of insomnia.
  - Can be taken **with or without food**.
  - **Shake the suspension well** before each dose to ensure even distribution.
  - **Measure dose accurately** using a provided oral syringe or dosing cup—do not use household spoons.
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## Side Effects

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## 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.
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## 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.

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## Additional Information

- **Contraindications:**

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