

Dyanavel XR (Amphetamine) – Patient Information Handout

What is Dyanavel XR?

Dyanavel XR is a prescription medicine used to treat Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older. It is a long-acting (extended-release) stimulant medication that works throughout the day with just one dose each morning. It is available as a liquid (oral suspension) or a tablet.

How to Take Dyanavel XR

- Take it **once daily in the morning**, with or without food.
 - **Liquid (oral suspension):** Shake the bottle well before every dose. Use only the oral dosing dispenser provided by your pharmacist. Do not remove the bottle adapter once it has been inserted.
 - **Tablets:** May be chewed or swallowed whole. The 5 mg tablet can be split in half at the score line if needed.
 - Do not change your dose or stop taking Dyanavel XR without talking to your doctor.
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Common Side Effects

The following side effects are common and may improve over time:

- Decreased appetite or weight loss
- Dry mouth
- Stomach pain or nausea
- Trouble sleeping (insomnia)
- Restlessness or mood changes
- Dizziness

- Nosebleeds (especially in children)
- Fast heartbeat

Talk to your doctor if any of these side effects bother you or do not go away.

Serious Side Effects — Call Your Doctor Right Away If You Experience:

- **Heart problems:** Chest pain, shortness of breath, fainting, or a very fast or irregular heartbeat.
 - **Mental health changes:** New or worsening behavior or thought problems, new psychotic symptoms (such as hearing voices or seeing things that are not real), or new manic symptoms.
 - **Circulation problems in fingers and toes:** Numbness, pain, coolness, or skin color changes (pale, blue, or red) in your fingers or toes. Report any unexplained wounds on fingers or toes immediately.
 - **Serotonin syndrome** (especially if taking antidepressants): Agitation, hallucinations, fast heartbeat, fever, muscle stiffness, twitching, nausea, vomiting, or diarrhea.
 - **Severe allergic reaction:** Rash, hives, swelling of the face or throat, or difficulty breathing.
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Important Safety Information

- **Do not take Dyanavel XR** if you are taking or have taken a monoamine oxidase inhibitor (MAOI) within the last 14 days, or if you are allergic to amphetamine or any ingredient in Dyanavel XR.
- Tell your doctor about all medications you take, especially antidepressants (SSRIs, SNRIs, tricyclics), migraine medicines (triptans), lithium, tramadol, fentanyl, or St. John's Wort, as these may increase the risk of serotonin syndrome.
- Dyanavel XR may raise blood pressure and heart rate. Your doctor should check these regularly.

- In children, Dyanavel XR may slow growth (height and weight). Your doctor should monitor your child's growth during treatment.
 - Tell your doctor if you or your child has a history of heart problems, high blood pressure, mental health problems, tics, or Tourette's syndrome.
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Storage and Safety

- Store Dyanavel XR in a safe place, preferably locked, to prevent misuse or theft.
 - Never share Dyanavel XR with anyone else — it is a controlled substance and sharing it is illegal and dangerous.
 - Dispose of any unused medication properly. Ask your pharmacist how to do this safely.
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When to Seek Emergency Help

Go to the nearest emergency room or call 911 if you experience:

- Chest pain or difficulty breathing
 - Fainting or seizures
 - Signs of a severe allergic reaction (swelling of face/throat, difficulty breathing)
 - Signs of overdose (restlessness, tremor, rapid breathing, confusion, hallucinations, fever)
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Questions?

If you have questions about Dyanavel XR, talk to your doctor or pharmacist. You can also report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.