For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older

Dyanavel® XR (amphetamine) extended-release oral suspension 2.5 mg/mL

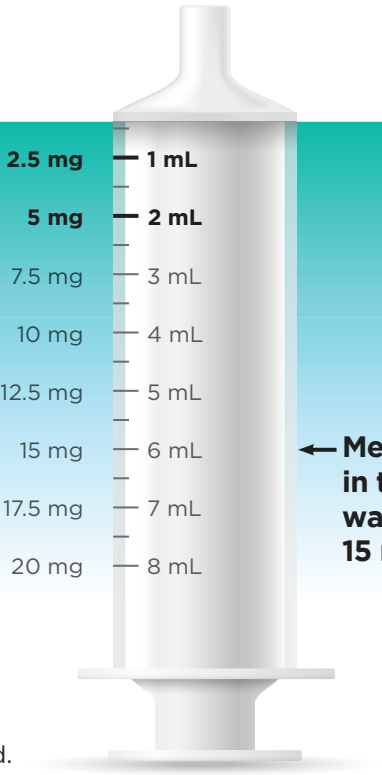
Help your ADHD patients balance efficacy and side effects

DYANAVEL® XR (amphetamine) is designed for optimized dosing and titration in 1 prescription[1]

STARTING DOSE
2.5 mg (1 mL) or 5 mg (2 mL)

ADJUST THE DOSE
in increments of 2.5 mg (1 mL) to 10 mg (4 mL) per day, every 4 to 7 days, until optimal response is reached.

20 mg (8 mL) maximum daily dose



Mean optimal dose in the clinical trial was approximately 15 mg per day[2]

1 mL of DYANAVEL XR=2.5 mg of amphetamine base.
Shake bottle well before administration.
Taken orally once daily in the morning, with or without food.

Visit TrisADHDhcp.com/dyanavel-xr for more information.

Eligible patients may pay **$25** for their prescription.
Access copay cards at **coupon.trisadhd.com**. Terms and conditions apply.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

DYANAVEL XR has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including DYANAVEL XR, can result in overdose and death. Before prescribing DYANAVEL XR, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout treatment, reassess each patient's risk and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

Please see additional Important Safety Information on the next page and product Full Prescribing Information, including Boxed Warning regarding Abuse, Misuse, and Addiction.

Co-pay savings are available for eligible patients.
Visit coupon.trisadhd.com to learn more.

Dyanavel® XR (II)
(amphetamine) extended-release oral suspension 2.5 mg/mL

IMPORTANT SAFETY INFORMATION (CONT'D)

- DYANAVEL XR (amphetamine) is contraindicated:
  - in patients known to be hypersensitive to amphetamine, or other components of DYANAVEL XR. Hypersensitivity reactions, such as angioedema and anaphylactic reactions, have been reported with other amphetamines.
  - in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of increased risk of hypertensive crisis.
- Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD doses. Serious cardiovascular effects with overdose may precipitate sudden cardiac death. Prior to treating patients with DYANAVEL XR, assess for the presence of cardiac disease. Avoid DYANAVEL XR use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during DYANAVEL XR treatment.
- CNS stimulants cause increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Monitor all patients for potential tachycardia and hypertension.
- Use of CNS stimulants may cause exacerbation of pre-existing psychosis and may induce a manic or mixed episode in patients with bipolar disorder. In patients without prior history of psychotic illness or mania, CNS stimulants may cause new psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) at the recommended dosage. Prior to initiating DYANAVEL XR treatment, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing DYANAVEL XR.
- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients with ADHD; monitor weight and height during treatment with DYANAVEL XR. Treatment may need to be interrupted in children not growing as expected.
- CNS stimulants, including DYANAVEL XR, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for DYANAVEL XR-treated patients who develop signs or symptoms of peripheral vasculopathy.
- Serotonin syndrome risk is increased when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans), MAOIs, and during overdosage situations. If it occurs, discontinue DYANAVEL XR and any concomitant serotonergic agents immediately, and initiate supportive treatment.
- CNS stimulants, including amphetamine, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. Before initiating DYANAVEL XR, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor DYANAVEL XR-treated patients for the emergence or worsening of tics or Tourette's syndrome and discontinue treatment if clinically appropriate.
- Most common adverse reactions observed with amphetamine products: dry mouth, anorexia, weight loss, abdominal pain, nausea, insomnia, restlessness, emotional lability, dizziness, and tachycardia. Based on limited experience with DYANAVEL XR in controlled trials, the adverse reaction profile of DYANAVEL XR appears similar to other amphetamine extended-release products. The most common (≥2% in the DYANAVEL XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 108 patients with ADHD (aged 6 to 12 years) were: epistaxis (DYANAVEL XR 4%, placebo 0%), allergic rhinitis (4%, 0%) and upper abdominal pain (4%, 2%).
- DYANAVEL XR use during pregnancy may cause fetal harm. To monitors pregnancy outcomes in women exposed to DYANAVEL XR during pregnancy, healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Psychostimulants at 1-866-961-2388 or visiting online at **https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/**.
- Because of the potential for serious adverse reactions in a breastfed infant, breastfeeding is not recommended during treatment with DYANAVEL XR.
- *To report SUSPECTED ADVERSE REACTIONS, contact Tris Pharma, Inc. at 1-732-940-0358 or FDA at 1-800-FDA-1088 or* **www.fda.gov/medwatch**.

Please see accompanying Full Prescribing Information for DYANAVEL XR, including Boxed Warning regarding Abuse, Misuse, and Addiction.

Visit TrisADHDhcp.com/dyanavel-xr for more information about DYANAVEL XR.

References: 1. Dyanavel XR [package insert]. Tris Pharma, Inc., Monmouth Junction, NJ. 2. Childress AC, Wigal SB, Brams MN, et al. *J Child Adolesc Psychopharmacol*. 2018;28(5):306-313.

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