For patients 6 years and older with Attention Deficit Hyperactivity Disorder (ADHD)

NOW AVAILABLE

Once-Daily DYANAVEL® XR (amphetamine) Tablet

Optimized dosing powered by Liqui*XR*® technology

- **Immediate-release (IR) and extended-release (ER) action, all in a single tablet**
- **Tablets must be taken in the morning, with or without food**
- **Dosing as low as 2.5 mg to help balance side effects and efficacy**

The only extended-release amphetamine tablet with up to 8 dosing options

5 mg

***First and only** scored ER amphetamine tablet*

10 mg

15 mg

20 mg

Tablets are shown at actual size.

DYANAVEL XR Tablet Dosing Considerations:

- Recommended starting dose is 2.5 mg or 5 mg once daily in the morning
- Adjust dose in 2.5-mg to 10-mg increments per day, every 4 to 7 days, until optimal response is achieved or maximum dose is reached
- The maximum recommended dosage is 20 mg once daily
- When switching to DYANAVEL XR (amphetamine), discontinue prior treatment and titrate to optimal dose; do not substitute for other amphetamine products on a milligram-per-milligram basis
- Prior to treatment, assess for the presence of cardiac disease and risk of abuse
- Keep prescription records; educate patients about abuse; and monitor for signs of abuse, dependence, and overdose
- Periodically reevaluate the need for, and long-term use of, DYANAVEL XR; adjust dose as needed

INDICATION

DYANAVEL XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including DYANAVEL XR, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

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

Once-daily DYANAVEL® XR (amphetamine) extended-release tablets 5 mg • 10 mg • 15 mg • 20 mg

For your patients 6 years and older with ADHD

Choose *DYANAVEL® XR (amphetamine)* Tablet

Tris Pharma is focused on patient support so *you* can focus on treatment

- Co-pay Savings Card*
- Text-to-Enroll Program†
- Pharmacy Locator Tool

See how DYANAVEL XR tablet can help your patients. Visit www.trisadhdhcp.com

*Terms and Conditions apply.
†Mobile Terms and Conditions: www.TrisMobileTC.com. Message data rates may apply.
PO, by mouth.

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, because of increased risk of hypertensive crisis
- Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. Sudden death, stroke and myocardial infarction have been reported in adults with CNS stimulant treatment at recommended doses. Sudden death has been reported in pediatric patients with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. 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 tachycardia and hypertension.
- CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a preexisting psychotic disorder. They may induce a mixed/manic episode in patients with bipolar disorder. Assess for presence of bipolar disorder prior to initiating treatment. At recommended doses, stimulants may cause psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania, in patients without prior history of psychotic illness or mania. If such 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.
- 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.
- 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.
- Breastfeeding is not recommended during treatment with DYANAVEL XR.

Please see Full Prescribing Information, including Boxed Warning regarding Abuse and Dependence.

Tris PHARMA

2031 U.S. 130, Monmouth Junction, NJ 08852

Once-daily
DYANAVEL® XR
(amphetamine) extended-release
tablets 5 mg • 10 mg • 15 mg • 20 mg