A Guide to **DYANAVEL® XR**() (amphetamine)

If afternoon ADHD symptoms are disrupting your day, meet the **continuous-release medication still working at 13 hours**¹



IMPORTANT SAFETY INFORMATION

DYANAVEL XR is a federally controlled substance (CII) because it contains amphetamine that can be a target for people who abuse prescription medicines or street drugs. DYANAVEL XR has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Keep DYANAVEL XR in a safe place to prevent abuse and misuse. Never give your DYANAVEL XR to anyone else because it may cause death or harm them. Selling or giving away DYANAVEL XR may harm others and is against the law.

- Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with DYANAVEL XR and will monitor you or your child during treatment.
- Tell your physician if you, your child, or any family members have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

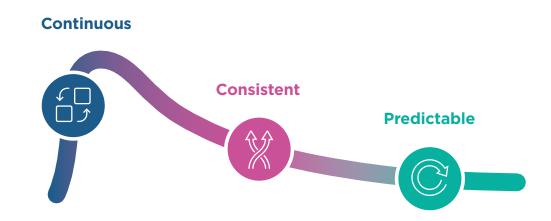
DYANAVEL XR should not be taken if you or your child are allergic to amphetamine or any of the ingredients in DYANAVEL XR or are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI including the antibiotic linezolid and the intravenous medicine methylene blue.

Please see additional Important Safety Information throughout, and <u>Full Prescribing Information</u>, including BOXED WARNING regarding ABUSE, MISUSE, and ADDICTION and <u>Medication Guide</u>.

DYANAVEL XR is a continuous-release amphetamine



If you need your ADHD medication to work consistently - **through the day, every day** - DYANAVEL XR may be able to help.



DYANAVEL XR is proven to effectively control ADHD symptoms throughout the day¹

WHAT IS DYANAVEL XR?

DYANAVEL XR is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years and older. DYANAVEL XR may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if DYANAVEL XR is safe and effective in children under 6 years of age.

IMPORTANT SAFETY INFORMATION (cont'd)

DYANAVEL XR can cause serious side effects including:

• **Risks for people with serious heart disease:** Sudden death has happened in people who have heart defects or other serious heart disease. Before starting DYANAVEL XR, tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with DYANAVEL XR.

Increase in blood pressure and heart rate.

Your healthcare provider should check your or your child's blood pressure and heart rate regularly during treatment with DYANAVEL XR.

 Mental (psychiatric) problems, including new or worse behavior and thought problems, new or worse bipolar illness, new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms.

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression. **Call the doctor right away if there are any new or worsening mental symptoms during treatment.**

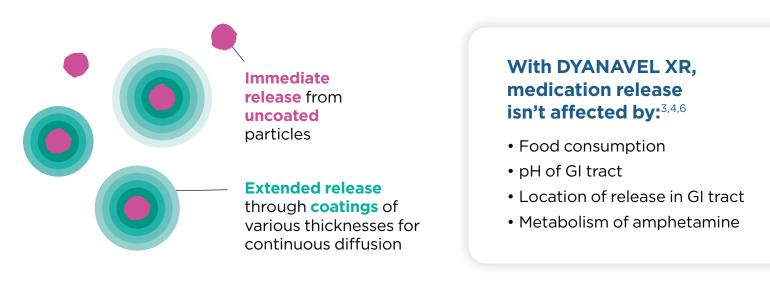
ADHD afternoon symptom rebound quiz



1	Do your ADHD symptoms return in the afternoon?	Yes / No	In a recent survey, barely
2	Are you irritable or exhausted when your ADHD medication stops?	Yes / No	half of adult ADHD patients were satisfied with duration of their current extended release medication. ²
3	Would you like your ADHD medication to last longer?	Yes / No	

How is DYANAVEL XR different?

DYANAVEL XR (amphetamine) is made with an advanced delivery system that continuously releases medication.3-5



IMPORTANT SAFETY INFORMATION (cont'd)

· Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon). Tell your healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call the doctor right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with DYANAVEL XR.

 New or worsening tics or worsening Tourette's syndrome. Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with DYANAVEL XR.

Please see additional Important Safety Information throughout, and Full Prescribing Information, including BOXED WARNING regarding **ABUSE, MISUSE, and ADDICTION and Medication Guide.**



Switching to DYANAVEL XR (amphetamine)



Talk to your doctor about your ADHD and your symptoms in the afternoon and evening



Request DYANAVEL XR

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If appropriate, your doctor will start you on DYANAVEL XR and titrate until you reach the **correct dose**



Pay as little as \$25 for your prescription if covered on your commercial insurance - see back cover for details.

Get ready for... Smooth, predictable drug release with no drop-off in the afternoon^{3,4}

IMPORTANT SAFETY INFORMATION (cont'd)

- Serotonin Syndrome. This problem may happen when DYANAVEL XR is taken with certain other medicines and may be life-threatening. Stop taking DYANAVEL XR and call your healthcare provider or go to the nearest hospital emergency room if you get symptoms such as agitation, hallucinations, coma, or other changes in mental status; fast heartbeat; sweating or fever; nausea, vomiting, diarrhea; high or low blood pressure; problems controlling movements or muscle twitching; muscle stiffness or tightness.
- Slowing of growth (height and weight) in children. Children should have their height and weight checked often during treatment with DYANAVEL XR. Your healthcare provider may stop your child's DYANAVEL XR treatment if they are not growing or gaining weight as expected.
- It is not known if DYANAVEL XR will harm the unborn baby. There is a pregnancy registry for females who are exposed to DYANAVEL XR during pregnancy. The purpose of the registry is to collect information about the health of females exposed to DYANAVEL XR and their baby. If you or your child becomes pregnant during treatment with DYANAVEL XR, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388 or visit <u>https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/othermedications/</u>.
- DYANAVEL XR passes into breast milk. You or your child should not breastfeed during treatment with DYANAVEL XR. Tell your doctor if you are breastfeeding or plan to breastfeed.

The most common side effects of amphetamine products include:

- drv mouth
- stomach pain
- restlessness
 extreme mood changes

- decreased appetite
 weight loss
- nausea
 trouble sleeping
- dizziness

increased heart rate

Talk to your doctor if you or your child have any side effects that bother you or do not go away.

Please see additional Important Safety Information throughout, and <u>Full Prescribing Information</u>, including BOXED WARNING regarding ABUSE, MISUSE, and ADDICTION and <u>Medication Guide</u>.

Affordable



What will I pay?

- \$25 per month with co-pay card if covered on your commercial insurance*
- **\$100** per month if you have commercial insurance that does not cover DYANAVEL XR. Ask pharmacist to submit claim to primary third-party payer first, then submit balance due to Capital Rx as a Secondary Payer as a copay-only billing using a valid Other Coverage Code*
- \$150 per month if you are paying with cash*



To learn more, visit coupon.trisadhd.com

*Co-pay offer is subject to eligibility. Terms and Conditions apply

For more information on DYANAVEL XR, visit www.DYANAVEL.com

IMPORTANT SAFETY INFORMATION (cont'd)

Avoid drinking alcohol while taking DYANAVEL XR.

To report SUSPECTED ADVERSE REACTIONS, contact Tris Pharma, Inc. at (732) 940-0358 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. Childress AC, Wigal SB, Brams MN, et al. Efficacy and safety of amphetamine extended release oral suspension in children with attention-deficit/hyperactivity disorder. *J Child Adolesc Psycholpharmacol.* 2018;28(5):306-313. **2.** ADDitude. Special Report: ADHD Treatments Scorecard from ADDitude Readers. Spring 2024 Issue. Available at: https:// www.additudemag.com/adhd-treatments-scorecard-medication-therapy-supplementsexercise/ **3.** Pardo A, Kando JC, King TR, Rafla E, Herman BK. Single-dose pharmacokinetics of amphetamine extended-release tablets compared with amphetamine extended-release oral suspension. *CNS Spectr.* 2020;25(6):774-781. **4.** Cutler AJ, Hanaie J. Understanding the delivery technology used in ADHD stimulant medications can help to individualize treatment. *CNS Spectrums.* 2025;30(1):e30. **5.** DYANAVEL XR [package insert]. Tris Pharma, Inc., Monmouth Junction, NJ. **6.** Powell JJ, Greenfield SM, Thompson RP. Concentrations of metals in gastric juice in health and peptic ulcer disease. *Gut.* 1992;33(12):1617-1620.

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