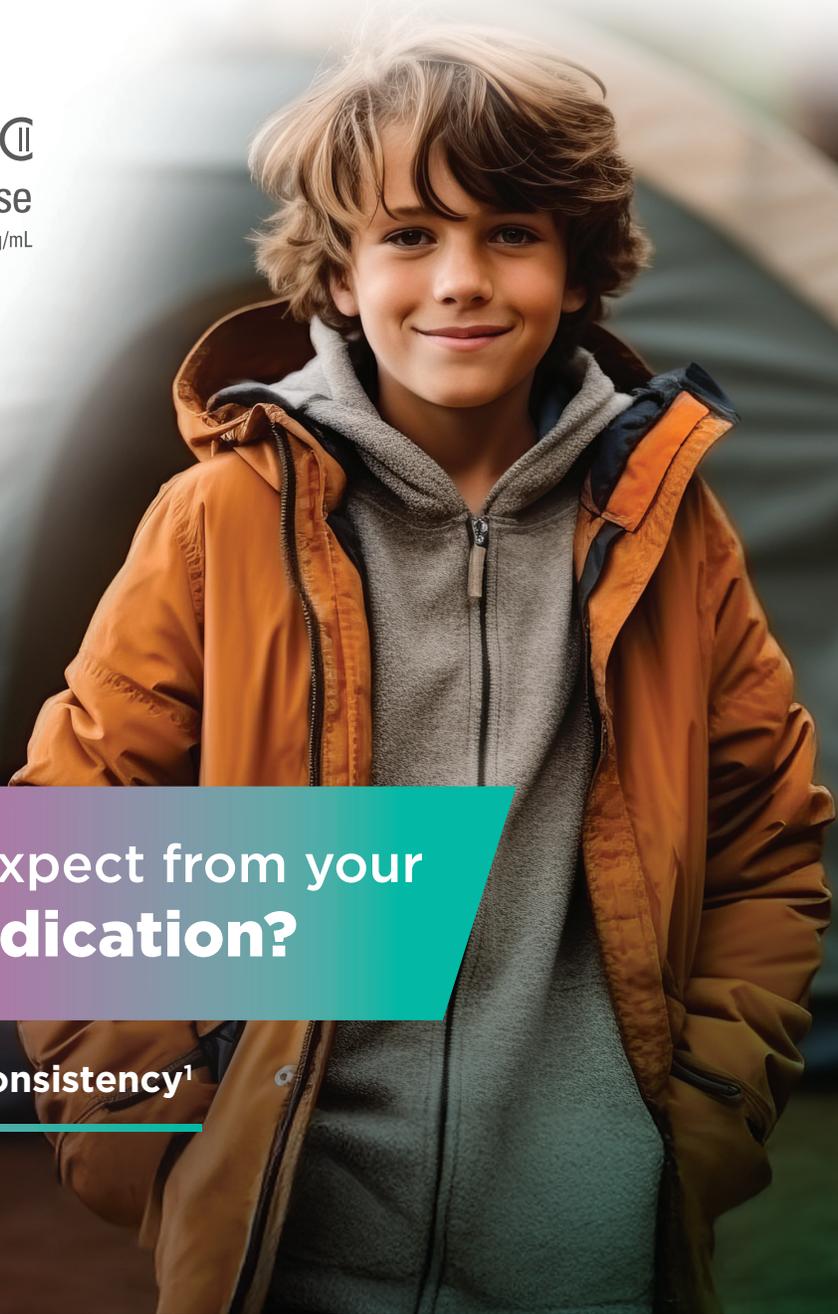


For people 6 years and older with Attention Deficit Hyperactivity Disorder (ADHD)

DYANAVEL[®]XR **Ⓜ**
(amphetamine) extended-release
tablets 5 mg • 10 mg • 15 mg • 20 mg | oral suspension 2.5 mg/mL



What should you expect from your
child's **ADHD medication?**

DYANAVEL[®] XR delivers: Consistency¹

IMPORTANT SAFETY INFORMATION

DYANAVEL[®] XR (amphetamine) 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.

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

If your child has ADHD, you're not alone



~5 million children in the US have a current diagnosis of ADHD²



While ADHD can affect different areas of your child's life, many treatment options are available to help your child manage symptoms.^{3,4}

Stimulant medications are often prescribed to help the symptoms of ADHD, but many factors can impact how people respond to some stimulants.^{3,4}

- **DYANAVEL XR (amphetamine) is a stimulant medication designed to provide continuous medication release through the day.**^{5,6}
- **Available in both Liquid and Tablet formulations that allow your doctor to start your child at a low dose and easily adjust the dose to meet your child's specific needs.**⁵

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)

- 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.

Discover a personalized approach to your child's ADHD treatment

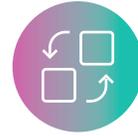
DYANAVEL XR (amphetamine) is designed to provide:



Flexible dosing tailored to your child's needs⁵



13 hours of symptom control⁷



Continuous, smooth medication release through the day^{5,6}

Unique Technology: Consistent Control

DYANAVEL XR is uniquely designed for continuous medication release through the day^{5,6}

Many factors can affect how people respond to ADHD medications. Our technology was designed to release medication consistently—through the day, every day. With DYANAVEL XR, each extended-release particle has a unique protective coating, so release of amphetamine is **not affected by**^{1,4,5,6,8}:



Food consumption



Location of release in the GI tract



pH of GI tract



Metabolism of amphetamine



Smooth and consistent^{1,6}

- **Predictable symptom control**^{7,9}

With DYANAVEL XR, amphetamine is released by diffusion in a smooth and consistent way through the day^{1,5,6}

- **Won't disrupt your child's daily routine**

In a pharmacokinetic study, drug levels were similar whether DYANAVEL XR tablets were taken on an empty stomach or with food and whether chewed or swallowed^{1,5}

IMPORTANT SAFETY INFORMATION (cont'd)

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 [Full Prescribing Information](#), including **BOXED WARNING** about **ABUSE, MISUSE and ADDICTION**, and [Medication Guide](#).

Proven Efficacy Through the Day⁷

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The study

DYANA VEL XR (amphetamine) was studied to evaluate safety and symptom control throughout the day.^{5,7}



- Laboratory classroom study included 99 children aged 6 to 12 years with ADHD⁷
- Efficacy was assessed by teachers and raters using the SKAMP rating scale.*⁷
- The primary test result was the change in SKAMP-combined score at 4 hours after DYANA VEL XR was taken. Other test results looked at the change at 1, 2, 4, 6, 8, 10, 12, and 13 hours after DYANA VEL XR was taken.⁷

The results



- Proven 13 hours of efficacy⁷
- Continuous symptom control⁷
- Significant improvement in attention and behavior⁷

DYANA VEL XR demonstrated efficacy at treating ADHD in children, with an anticipated safety profile

*SKAMP is a 13-item, teacher-rated, 7-point, impairment rating scale that assesses manifestations of ADHD in a classroom setting⁷

DYANA VEL XR Savings Program

Ask your Doctor for a Savings Card!



Learn how you can pay as little as \$25* for your prescription at [trisadhd.com](https://www.trisadhd.com)

*Terms and conditions apply. Card issue is subject to eligibility. Visit <https://www.trisadhd.com/savings-and-support/> for details.

IMPORTANT SAFETY INFORMATION (cont'd)

DYANA VEL 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 DYANA VEL 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 DYANA VEL XR.**

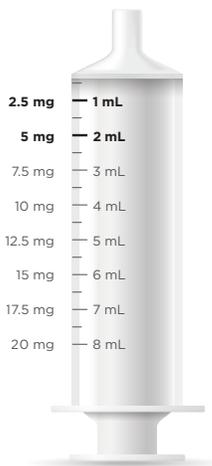
Available in Liquid and Tablet Formulations for Personalized Dosing⁵

DYANAVEL[®]XR (amphetamine) extended-release
tablets 5 mg • 10 mg • 15 mg • 20 mg | oral suspension 2.5 mg/mL

It's easy to change from DYANAVEL XR Oral Suspension to DYANAVEL XR Tablets - ask your doctor for more information!⁵

DYANAVEL XR Oral Suspension

Dosing options for DYANAVEL XR (amphetamine) Oral Solution can be adjusted in small amounts as prescribed by your doctor and directed by your pharmacist.



Did you know?

DYANAVEL XR is **bubblegum-flavored** in both liquid and tablet formulations.

Discover flexible dosing to meet your child's needs

- Your healthcare provider may start DYANAVEL XR at a low dose and individualize the dose by adjusting it up or down based on your child's treatment response
- DYANAVEL XR Oral Solution comes with an oral dosing dispenser that will help you measure the amount of medication
- DYANAVEL XR should be taken by mouth once every day in the morning
- DYANAVEL XR can be taken with or without food
- Take DYANAVEL XR Oral Solution exactly as prescribed and remember to shake the bottle well (up and down) prior to each use

DYANAVEL XR Tablets

With **four tablet dosing options** - including a 5 mg tablet that can be divided in two - your doctor can work with you to find what works for you.⁵

5 mg



Scored tablet may be split for 2.5 mg dose

10 mg



15 mg



20 mg



DYANAVEL XR tablet can be **swallowed or chewed**.⁵ Tablets are not shown at actual size.

How to take DYANAVEL XR

Read the Instructions for Use for DYANAVEL XR you received from your pharmacist before your child takes DYANAVEL XR and every time you get a refill so that you have the most up-to-date instructions.

If you have any questions, talk to your healthcare provider about your child's medical condition or treatment.

Please see **Medication Guide** and **Instructions for Use** in the accompanying **Full Prescribing Information** for specific instructions on how your child should take DYANAVEL XR.

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

IMPORTANT SAFETY INFORMATION (cont'd)

DYANAVEL XR (amphetamine) can cause serious side effects including (cont'd):

- **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.**
- **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.
- **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 <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/>.
- 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:

- | | | | |
|----------------------|--------------------|------------------------|------------------------|
| - dry mouth | - stomach pain | - restlessness | - dizziness |
| - decreased appetite | - nausea | - extreme mood changes | - increased heart rate |
| - weight loss | - trouble sleeping | | |

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

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.

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DYANAVEL XR Delivers!

13 hours of symptom control⁷

Continuous release through the day^{5,6}

Flexible dosing tailored to your child's needs⁵

To learn more about **DYANAVEL XR (amphetamine)**
tablets, visit dyanavel.com

References: **1.** 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. **2.** Danielson M. Prevalence of Parent-Reported ADHD Diagnosis and Associated Treatment Among U.S. Children and Adolescents, 2016 *J Clin Child Adolesc Psychol*. 2018 ; 47(2): 199-212. doi:10.1080/15374416.2017.1417860. **3.** American Academy of Pediatrics. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. 2019. Available at: <https://publications.aap.org/pediatrics/article/144/4/e20192528/81590/Clinical-Practice-Guideline-for-the-Diagnosis?autologincheck=redirected>. **4.** Ermer JC, Adeyi BA, Pucci ML. Pharmacokinetic variability of long-acting stimulants in the treatment of children and adults with attention-deficit hyperactivity disorder. *CNS Drugs*. 2010;24(12):1009-1025. **5.** DYANAVEL XR [package insert]. Tris Pharma, Inc., Monmouth Junction, NJ. **6.** Cutler AJ, Hanaie J. Understanding the delivery technology used in ADHD stimulant medications can help to individualize treatment. *CNS Spectrums*. 2025;30(1):e30. **7.** 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 Psychopharmacol*. 2018;28(5):306-313. **8.** Powell JJ, Greenfield SM, Thompson RP. Concentrations of metals in gastric juice in health and peptic ulcer disease. *Gut*. 1992;33(12):1617-1620. **9.** Cutler AJ, Childress AC, Pardo A, et al. Randomized, double-blind, placebo-controlled, fixed-dose study to evaluate the efficacy and safety of amphetamine extended-release tablets in adults with attention-deficit/hyperactivity disorder. *J Clin Psychiatry*. 2022;83(5):22m14438.

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