

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

DYANAVEL[®]XR CII

(amphetamine) extended-release

🍬 tablets 5 mg • 10 mg • 15 mg • 20 mg | 💧 oral suspension 2.5 mg/mL



JUST
ONE

One Dose. One Full Day of ADHD symptom control
for kids and adults.

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](#).



Living with ADHD can be challenging, but you and your child are not alone



In the US,

~11% of children have a current ADHD diagnosis¹

~6% of adults are affected by ADHD²

ADHD isn't just about work or school — it can cause symptoms throughout the day and into the evening, affecting many different areas³

Stimulants are often recommended for patients with ADHD, but many factors can affect how people respond to some medications. Not all stimulant medications work the same or last for the same amount of time.^{3,4}

If you need your ADHD medication to work consistently — through the day, every day — DYANAVEL XR (amphetamine) may be able to help due to its unique formulation.

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.

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DYANAVEL XR delivers **consistency**

Discover advanced ADHD drug delivery with DYANAVEL XR (amphetamine), and get 13 hours of ADHD symptom control through the day with just one daily dose.⁵

Clinical and real-world studies show:



Proven symptom control lasting up to 13 hours⁵



Smooth, continuous release through the day^{6,7}



Associated with reduced use of IR boosters at 90 days⁸

How is DYANAVEL XR different?

DYANAVEL XR is made with an advanced delivery system that continuously releases medication.^{6,7}

Immediate release
from **uncoated** particles

Extended release
through **coatings** of
various thicknesses for
continuous diffusion

**With DYANAVEL XR,
medication release
isn't affected by:**^{6,7,9}

- Food consumption
- pH of GI tract
- Location of release in GI tract
- Metabolism of amphetamine

Visit dyanavelxr.com to see
how DYANAVEL XR works

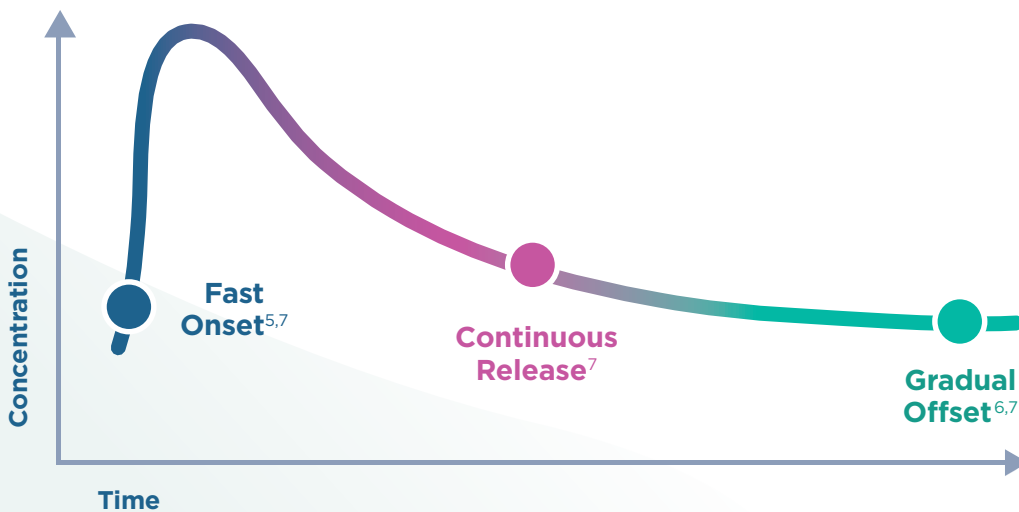
IMPORTANT SAFETY INFORMATION (cont'd)

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 a medicine called a monoamine oxidase inhibitor or (MAOI) including the antibiotic linezolid and the intravenous medicine methylene blue. Ask your healthcare provider or pharmacist if you are not sure if you or your child take any of these medicines.

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DYANAVEL XR is a continuous-release amphetamine

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



In a real-world study, DYANAVEL XR was linked to fewer end-of-dose crashes when the medication wears off.⁸

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.

DYANAVEL XR 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 with DYANAVEL XR, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

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Proven EFFICACY

DYANAVEL XR works
FOR 13 HOURS^{5,11}



DYANAVEL XR study in children

DYANAVEL XR (amphetamine) was studied to evaluate safety and symptom control throughout the day.^{5,10}



- Laboratory classroom study included 99 children aged 6 to 12 years with ADHD⁵
- Efficacy was assessed by teachers and raters using the SKAMP rating scale*⁵
- The primary test result was the change in SKAMP-combined score at 4 hours after DYANAVEL was taken. Other test results looked at the change at 1, 2, 4, 6, 8, 10, 12, and 13 hours after DYANAVEL was taken⁵

The results



- Proven **13 hours** of efficacy⁵
- **Continuous** symptom control⁵
- **Significant** improvement in attention and behavior⁵

*SKAMP is a 13-item, teacher-rated, 7-point, impairment rating scale that assesses manifestations of ADHD in a classroom setting⁵

DYANAVEL XR study in adults

A double-blind study compared DYANAVEL XR Tablets with placebo.

91 adult participants completed the study by taking a series of Permanent Product Measure of Performance (PERMP) tests to measure attention and performance throughout the day.¹¹ The study showed:



- **DYANAVEL XR** delivers proven efficacy and consistent ADHD symptom control throughout the day¹¹

DYANAVEL XR demonstrated efficacy at treating ADHD, with common side effects as seen with other stimulants for ADHD.

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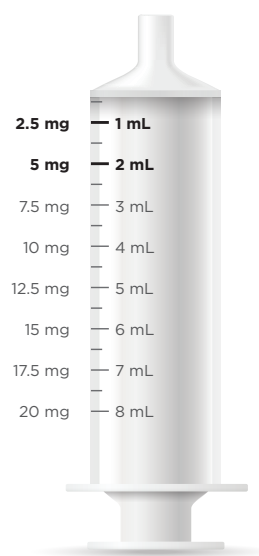
Available in **LIQUID**
and **TABLET**
formulations for
personalized dosing¹⁰



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DYANAVEL XR Oral Suspension

Dosing options for DYANAVEL XR (amphetamine) Oral Suspension can be adjusted in small amounts as prescribed.



Did you know?

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

With DYANAVEL XR, you
can easily switch from oral
suspension to tablets just
by asking your healthcare
provider.¹⁰

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 treatment response
- DYANAVEL XR Oral Suspension 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 Suspension 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 healthcare provider can work with you to find what works.¹⁰ DYANAVEL XR Tablets can be **swallowed or chewed**.¹⁰

5 mg



Scored tablet may be
split for 2.5 mg dose

10 mg



All tablets are not
shown at actual size.

15 mg



20 mg



How to take DYANAVEL XR

Read the Instructions for Use for DYANAVEL XR you received from your pharmacist before taking 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.

Please see **Medication Guide** and **Instructions for Use** for specific instructions on taking DYANAVEL XR.

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IMPORTANT SAFETY INFORMATION (cont'd)

DYANA VEL XR (amphetamine) can cause serious side effects including (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 DYANA VEL 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 DYANA VEL XR.
- **Serotonin Syndrome.** This problem may happen when DYANA VEL XR is taken with certain other medicines and may be life-threatening. Stop taking DYANA VEL 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 DYANA VEL XR. Your healthcare provider may stop your child's DYANA VEL XR treatment if they are not growing or gaining weight as expected.
- It is not known if DYANA VEL XR will harm the unborn baby. Before taking DYANA VEL XR, tell your health care provider if you are pregnant or plan to become pregnant. There is a pregnancy registry for females who are exposed to DYANA VEL XR during pregnancy. The purpose of the registry is to collect information about the health of females exposed to DYANA VEL XR and their baby. If you or your child becomes pregnant during treatment with DYANA VEL 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/>.
- DYANA VEL XR passes into breast milk. You or your child should not breastfeed during treatment with DYANA VEL XR. Tell your doctor if you are breastfeeding or plan to breastfeed.

The most common side effects of amphetamine products include:

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

These are not all of the possible side effects of DYANA VEL XR.

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 DYANA VEL XR.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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GUARANTEED
Availability.
FREE Delivery.

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(amphetamine) extended-release
 tablets 5 mg • 10 mg • 15 mg • 20 mg



**Ask your doctor how you can easily get your
DYANAVEL XR (amphetamine) Tablets**



GUARANTEED AVAILABILITY

Perigon Pharmacy 360 works directly with Tris Pharma to ensure DYANAVEL XR tablets are always available



FREE & FAST DELIVERY

DYANAVEL XR tablets will be delivered directly to the address of your choice with no delivery fee (signature required)



PATIENT SUPPORT

Call **1.844.698.2533** (California residents please call **1.850.874.2025**)

What will you pay?

- **PAY AS LITTLE AS \$25 PER MONTH** with copay savings program* if your commercial insurance covers DYANAVEL XR tablets
- **\$100 PER MONTH** for eligible patients who choose to pay cash**

LEARN MORE AT [DYANAVEL.COM/DELIVERED](https://dyanavel.com/delivered)

APPROVED USE

DYANAVEL XR (amphetamine) 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.

DYANAVEL XR is not recommended for use in children under 6 years of age with ADHD.

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ADHD afternoon symptom rebound quiz

- 1 Do your ADHD symptoms return in the afternoon? Yes / No
- 2 Do you find it difficult to focus later in the day on your current ADHD medication? Yes / No
- 3 Would you like your ADHD medication to last longer? Yes / No
- 4 Are you tired of planning your day around boosters? Yes / No

If any of these questions resonate with you, talk to your healthcare provider about how DYANA VEL XR could help.

Join our community!



Learn more



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Tris Savings Program

Ask your healthcare provider for a Savings Card!

Learn how you can pay as little as \$25* on each prescription at trissavingscard.com

* Terms and conditions apply. Card issue is subject to eligibility. Visit trissavingscard.com/terms for details.



References: **1.** Danielson ML, et al. ADHD Prevalence Among U.S. Children and Adolescents in 2022: Diagnosis, Severity, Co-Occurring Disorders, and Treatment. *Journal of Clinical Child & Adolescent Psychology*. 2024 53(3), 343-360 **2.** Staley BS, Robinson LR, Claussen AH, et al. Attention-Deficit/Hyperactivity Disorder Diagnosis, Treatment, and Telehealth Use in Adults — National Center for Health Statistics Rapid Surveys System, United States, October–November 2023. US Department of Health and Human Services. Centers for Disease Control and Prevention. MMWR. October 10, 2024. Vol. 73, No. 40. **3.** Jain R. Addressing diagnosis and treatment gaps in adults with attention-deficit/hyperactivity disorder. *Prim Care Companion CNS Disord*. 2017;19(5):17nr02153. **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.** Childress AC, 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. **6.** Pardo A, et al. Single-dose pharmacokinetics of amphetamine extended-release tablets compared with amphetamine extended-release oral suspension. *CNS Spectr*. 2020;25(6):774-781. **7.** Cutler AJ, Hanaie J. Understanding the delivery technology used in ADHD stimulant medications can help to individualize treatment. *CNS Spectrums*. 2025;30(1):e30. **8.** Young JL, Powell RN, Powell A, Welling LLM, Granata L, Saal J, Nash M. Extended-release amphetamine (Dyanavel XR) is associated with reduced immediate-release supplementation in adults with ADHD, regardless of baseline patient variables: a retrospective cohort analysis of medical treatment records. *BMC Psychiatry*. 2025 Jan 3;25(1):12. **9.** Powell JJ, Greenfield SM, Thompson RP. Concentrations of metals in gastric juice in health and peptic ulcer disease. *Gut*. 1992;33(12):1617-1620. **10.** DYANAVEL XR [package insert]. Tris Pharma, Inc., Monmouth Junction, NJ. **11.** 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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