

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



Dyanavel[®]XR[Ⓢ]
(amphetamine) extended-release
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.

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) oral suspension is a stimulant medication in liquid form. This allows 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.

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 control⁶



Continuous, smooth medication release through the day^{5,7}

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.

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.

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.

Please see additional Important Safety Information throughout, and [Full Prescribing Information](#), including Boxed Warning regarding Abuse, Misuse, and Addiction.

Unique Technology: Consistent Control



DYANAVEL XR (amphetamine) is uniquely designed for continuous medication release through the day^{5,7}

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**^{1,4,5,7,8}:



Timing or type of food your child consumes



pH of GI tract



Where it is released in the GI tract



Amphetamine metabolism



Smooth and consistent^{1,7}

- **Predictable symptom control**

With DYANAVEL XR, amphetamine is released by diffusion in a smooth and consistent way through the day^{1,5,7}

- **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^{1,5,7}

IMPORTANT SAFETY INFORMATION (cont'd)

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.**

Proven All-Day Efficacy⁶



The study

DYANAVEL XR (amphetamine) was studied to evaluate safety and symptom control throughout the day.⁶



- Laboratory classroom study included 99 children aged 6 to 12 years with ADHD⁶
- Efficacy was assessed by teachers and raters using the SKAMP rating scale.*⁶
- 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 taken.⁶

The results



- Proven 13 hours of efficacy⁶
- Continuous symptom control⁶
- Significant improvement in attention and behavior⁶

DYANAVEL 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 setting⁶

IMPORTANT SAFETY INFORMATION (cont'd)

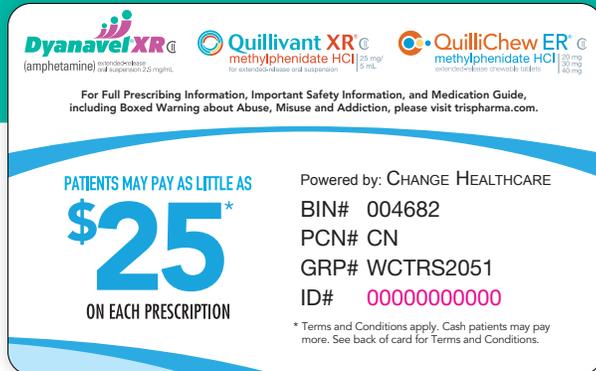
DYANAVEL XR can cause serious side effects including (cont'd):

- **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 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.

DYANAVEL XR (amphetamine) 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)

DYANAVEL XR can cause serious side effects including (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 <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
- decreased appetite
- weight loss
- stomach pain
- nausea
- trouble sleeping
- restlessness
- extreme mood changes
- 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. Avoid drinking alcohol while taking DYANAVEL XR.

Why a liquid? Individualized dosing!⁵



Discover flexible dosing to meet your child's needs

- Your healthcare provider may start DYANAVEL XR (amphetamine) at a low dose and individualize the dose by adjusting it up or down based on your child's treatment response
- DYANAVEL XR 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 exactly as prescribed and remember to shake the bottle well (up and down) prior to each use

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.

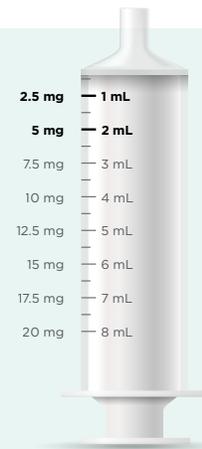
If you have any questions, talk to your healthcare provider about your child's medical condition or treatment.

Dosing options

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

Did you know?

DYANAVEL XR is bubblegum-flavored.



Please click to see [Instructions for Use](#) in the [Full Prescribing Information](#) for specific instructions on how your child should take DYANAVEL XR.

For full instructions you can visit

www.trisadhd.com/dyanavel-xr-liquid/taking-dyanavel-xr-liquid/

IMPORTANT SAFETY INFORMATION (cont'd)

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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



Should you expect more from your child's ADHD medication?

DYANAVEL XR Delivers!

13 hours of symptom control⁶

Continuous release through the day^{5,7}

Flexible dosing tailored to your child's needs⁵

LEARN MORE ABOUT DYANAVEL XR (amphetamine) oral suspension at [trisadhd.com/dyanavel-xr-liquid/](https://www.trisadhd.com/dyanavel-xr-liquid/)

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.** 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. **7.** Kando JC, King TR, Pardo A. A novel, modified release drug delivery technology containing amphetamine and methylphenidate ion-exchange complexes. Poster presented at: American Psychiatric Association Annual Meeting; May 1-3, 2021. **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.

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