

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

Discover an ADHD medicine

Designed for the home stretch

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 about Abuse, Misuse and Addiction](#), and [Medication Guide](#).

Living with adult ADHD can be challenging, but you're not alone



ADHD affects ~6% of adults in the US¹



ADHD in adults isn't just about work or school — it can cause symptoms throughout the day and into the evening, affecting different areas of your life²

Stimulants are often recommended for adult 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.^{2,3}

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

**When you're ready for consistency,
It's time for DYANAVEL XR**

An amphetamine with **unique technology** designed to give you:



Continuous
release of
amphetamine
through the day^{4,5}



Consistent,
smooth drug
delivery^{4,6}



Predictable,
long-lasting
symptom
control^{7,8}

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.

DYANAVEL XR (amphetamine) is uniquely designed for consistent drug release

Many factors can affect how stimulant medications for ADHD work. 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**^{4,5,6,9}:



Food consumption



Location of release in GI tract



pH of GI tract



Metabolism of amphetamine



Smooth drug release^{4,5,7} for predictable symptom control^{7,8}

- **Predictable symptom control**^{7,8}

With DYANAVEL XR, amphetamine is released by diffusion in a smooth and consistent way through the day^{4,6}

- **Works with your daily routine**

In a pharmacokinetic study, drug levels were similar whether DYANAVEL XR was taken on an empty stomach or with food and whether chewed or swallowed^{4,6}

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.

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.

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Long-lasting ADHD symptom control

The double-blind study compared DYANAVEL XR (amphetamine) oral suspension with placebo. The study showed:



- **DYANAVEL XR** worked at every timepoint measured in the study and was still working at 13 hours⁸
- **Consistent** ADHD symptom control throughout the day⁸

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

Dosing to meet your needs

With **four 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.⁶



DYANAVEL XR tablet can be **swallowed or chewed**.⁶



Also available as an oral suspension. Learn more at dyanavelxr.com/dyanavel-xr-liquid/

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.**

Guaranteed Availability, Free Delivery



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).



FULL PATIENT SUPPORT

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

What will you pay?



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

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

IMPORTANT SAFETY INFORMATION (cont'd)

DYANAVEL 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 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.

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Prefer your local pharmacy?

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Ask your Doctor for a Savings Card!

Insured Patients with Coverage May Pay As Little As

\$25*

Patients without coverage can save up to the program maximum benefit.

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

*Terms and Conditions apply. **Eligible patients may pay as little as \$25 each month.** See back of card for Terms and Conditions.

For Full Prescribing Information, Important Safety Information, and Medication Guide, including Boxed Warning about Abuse, Misuse and Addiction, please visit trispharma.com

BIN# [XXXXXX] PCN# [XXXX] GRP# WCTRS6503 ID# [XXXXXXXXXX]

- **\$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**

LEARN MORE AT COUPON.TRISADHD.COM

***RESTRICTIONS:** This offer is valid in the United States and Puerto Rico. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). Cash Discount Cards and other noninsurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. It is illegal to (or offer to) sell, purchase, or trade this offer. This offer is not transferable and is limited to one offer per person. Not valid if reproduced. Void where prohibited by law. Tris Pharma reserves the right to rescind, revoke, or amend this offer without notice at any time. See additional terms and conditions at coupon.trisadhd.com

****Cash Offer:** Patients are eligible to participate if the patient has no insurance or is underinsured such that the patient's applicable insurance does not adequately cover the cost of Dyanavel. Only valid through the Dyanavel Delivered by Perigon program.

Not for patients with prescription insurance through State Medicaid or Managed Medicaid plans. For patients with other government insurance, the patient must agree in writing to not submit a claim for reimbursement to any government insurance program and commit to paying the cash price through the end of the defined plan year. Patients may not count the cash price paid via the Cash Offer as an expense incurred for purposes of determining out-of-pocket costs for any government insurance plan, including true out-of-pocket costs (TrOOP), for purposes of calculating the out-of-pocket spending threshold or triggering catastrophic coverage for Medicare Part D plans.

Visit dyanavel.com/delivered for full terms and conditions.

IMPORTANT SAFETY INFORMATION (cont'd)

- **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

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Continuous release of amphetamine^{4,5}

Consistent, smooth drug delivery^{4,6}

Proven symptom control through the day^{7,8}

Guaranteed availability, low cost, and free, fast delivery with DYANAVEL Delivered

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

IMPORTANT SAFETY INFORMATION (cont'd)

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.

References: **1.** 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. **2.** Jain R. Addressing diagnosis and treatment gaps in adults with attention-deficit/hyperactivity disorder. *Prim Care Companion CNS Disord*. 2017;19(5):17nr02153. **3.** 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. **4.** 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. **5.** 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. **6.** Dyanavel XR [package insert]. Tris Pharma, Inc., Monmouth Junction, NJ. **7.** 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. **8.** 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. **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.

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