

Considering medication for your child with ADHD?



WHAT IS DYANAVEL XR?

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.**

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

IMPORTANT SAFETY INFORMATION

DYANAVEL XR is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep DYANAVEL XR in a safe place to prevent misuse and abuse. Selling or giving away DYANAVEL XR may harm others, and is against the law. Tell your physician if you, your child, or any family members have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Please see additional Important Safety Information throughout, and product <u>Full Prescribing Information</u>, including Boxed Warning regarding Abuse and Dependence.



So your child has ADHD? You're not alone.

ADHD is a neurodevelopmental disorder that affects more than 5 million school-aged children, tends to run in families, and often persists into adulthood.

But for you, ADHD isn't about the numbers. It's about one child—yours.

ADHD is definitely not one-size-fits-all.

The fact is, ADHD takes different forms in different children, with inattention and hyperactivity/impulsivity often going together. Any child may display some of these characteristics from time to time—which is why only a health care professional can diagnose ADHD.

You'll probably notice that the behaviors associated with ADHD can change with different activities throughout the day. For a child to be diagnosed with ADHD, they'll consistently have difficulty in more than one everyday setting—such as school, after-school activities, and home.

What symptoms are you seeing in your child right now?

Review with your child's doctor and teachers.

Inattentive	Hyperactive	Impulsive
Easily distracted	Squirms and fidgets in their seat Can't stay in a seat even when expected Runs, dashes around, or climbs in inappropriate	Takes hasty, poorly judged actions
Zones out when they need		
to focus		Blurts out answers without thinking and interrupts constantly
Avoids or resists tasks or		
doesn't follow through		
Makes careless mistakes		Has trouble waiting
Has a hard time listening, even when spoken to directly Loses things	Constantly on the go, as if driven by motor	Intrudes on other people's activities or conversations
	Seems unable to play or to occupy themselves quietly	
	Makes careless mistakes Has a hard time listening, even when spoken to directly	climbs in inappropriate situations Constantly on the go, as if driven by motor Talks nonstop Seems unable to play or to

(This is not a complete list of symptoms.)

IMPORTANT SAFETY INFORMATION (cont'd)

DYANAVEL XR (amphetamine) 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.

Finding the right treatment for your child with ADHD.

There are several options to help manage your child's symptoms. Treatments range from behavioral intervention to prescription medicine. Your child's treatment plan may include several of these options. Medicine is often an important part of treatment for a child with ADHD. American Academy of Pediatrics (AAP) guidelines recommend stimulants for children 6 years and older with ADHD. You and your doctor should work together to decide if medicine is a good option for your child.



Is ADHD medicine the answer for my child?

It's never an easy decision to start a child on medication. So let's look at why medicine may play an important role in your child's treatment plan, whether they're taking ADHD medication for the first time or switching from another ADHD medication. Stimulants have been shown to improve a child's symptoms. For children with ADHD who respond to stimulants, medicine that works for them can make a real difference.

Stimulants for my child with ADHD? Explain, please.

It's true. Stimulant medication is the treatment most often recommended for ADHD because many studies have shown it to be highly effective. ADHD medicines improve attention by helping brain chemicals work better. While the exact way stimulants work in ADHD is not known, they're believed to increase the brain chemicals dopamine and norepinephrine, which in turn helps reduce symptoms.

IMPORTANT SAFETY INFORMATION (cont'd)

DYANAVEL XR (amphetamine) can cause serious side effects. Tell the doctor:

• if you or your child have heart problems, heart defects, high blood pressure, or a family history of these problems. This is important because sudden death has occurred in children 6 to 17 years old with heart problems or defects, and sudden death, stroke, and heart attack have happened in adults. Your doctor should check you or your child carefully for heart problems before starting DYANAVEL XR. Since increases in blood pressure and heart rate may occur, the doctor should regularly check these during treatment. Call the doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking DYANAVEL XR.

Ask your doctor about DYANAVEL XR.

DYANAVEL XR (amphetamine) is a prescription medicine that may improve attention and behavior and help decrease impulsiveness and hyperactivity in people 6 years and older with ADHD.

As a concerned parent, you should know that the use of amphetamine products in treating children with ADHD has been well established. The amphetamine DYANAVEL XR has been studied in a clinical trial specifically in children aged 6 to 12 years who have been diagnosed with ADHD.* It has been approved for use in people with ADHD aged 6 years and older by the U.S. Food and Drug Administration (FDA).

*DYANAVEL XR was studied in a laboratory classroom setting in 108 children with ADHD aged 6 to 12 years, and was shown to significantly reduce the symptoms of ADHD. DYANAVEL XR provided ADHD symptom control as early as 1 hour and up to 13 hours after taking.

Why a liquid?

Every child is different. Doctors usually start by prescribing a low dose of a stimulant medicine. DYANAVEL XR is a liquid medication that allows your doctor to start low and adjust the dose up or down, slowly, in small amounts, without writing a new prescription. This enables the doctor to find the dose that helps improve your child's ADHD symptoms while minimizing side effects.

DYANAVEL XR uses the innovative, proprietary **LiquiXR*** technology from Tris Pharma. Your child takes the medicine once a day, in the morning, with or without food. Tris technology allows the medicine to be released slowly over the course of the day.



IMPORTANT SAFETY INFORMATION (cont'd)

- if you or your child have mental problems, or a family history of suicide, bipolar illness, or depression. This is important because new or worsening behavior and thought problems or bipolar illness may occur. New symptoms such as seeing or hearing things that are not real, believing things that are not true, being suspicious, or having new manic symptoms may occur. Call the doctor right away if there are any new or worsening mental symptoms during treatment.
- if you or your child have circulation problems in fingers and toes (called peripheral vasculopathy, including Raynaud's phenomenon). Fingers or toes may feel numb, cool, painful, sensitive to temperature, and/or change color from pale, to blue, to red. Call the doctor right away if any signs of unexplained wounds appear on fingers or toes while taking DYANAVEL XR.

Long lasting for your child. Flexible dosing for the doctor.



Starts working rapidly.

Morning can be a tough time for a child with ADHD. DYANAVEL XR (amphetamine) has been proven to start working quickly—as early as 1 hour after taking it.



Helps control symptoms from breakfast time through homework time.*

In a laboratory classroom study, DYANAVEL XR improved attention and behavior for up to 13 hours after taking it.*



Flexible dose adjustments

The dose can be tailored to your child's treatment needs.

Liquid DYANAVEL XR allows your doctor to adjust the dose, up or down, weekly in small amounts of 1 mL at a time.

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IMPORTANT SAFETY INFORMATION (cont'd)

- if your child is having slowing of growth (height and weight); Your child should have his or her height and weight checked often while taking DYANAVEL XR.
- if you or your child have symptoms of serotonin syndrome 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. Serotonin syndrome may occur when DYANAVEL XR is taken with certain other medicines and may be life-threatening. Stop DYANAVEL XR and call your doctor or go to the nearest hospital emergency room.
- if you or your child are pregnant or plan to become pregnant. It is not known if DYANAVEL XR will harm your unborn baby. Tell your doctor if you or your child become pregnant during treatment with DYANAVEL XR.
- if you or your child is breastfeeding or plan to breastfeed. DYANAVEL XR passes into breast milk. You or your child should not breastfeed while you are taking DYANAVEL XR.

Taking DYANAVEL XR.

DYANAVEL XR (amphetamine) should be taken exactly as prescribed by your doctor. For step-bystep instructions on how to administer a dose, please see the Instructions for Use in the Medication Guide. Ask your child's doctor or the pharmacist for any tips or advice.

What should you expect when your child is starting DYANAVEL XR?

Your child's doctor will introduce the medicine gradually so that your child can adapt to it. Get in touch with the doctor right away if you notice any side effects. In the clinical trial, side effects of DYANAVEL XR were nosebleeds, runny nose, and stomach pain.

These are not all the possible side effects of DYANAVEL XR. Please see the Important Safety Information on pages 3-6 for additional details.

Questions for your child's doctor about DYANAVEL XR.

- 1. What's the most important thing I need to know about DYANAVEL XR?
- 2. How should my child take DYANAVEL XR?
- 3. How can we be sure my child is getting the right dose?
- 4. What can we expect with DYANAVEL XR?

IMPORTANT SAFETY INFORMATION (cont'd)

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

Ask your child's school about a 504 plan.

A 504 plan specifies "accommodations"—academic, organizational, and social—that will be used to help a child access learning at school, based on a federal civil rights law that bans discrimination on the basis of disability.

The law applies to all schools and school districts that receive federal funding. A student qualifies for their own individual 504 plan if they have a documented disability that "substantially limits" their ability to learn.

For more information, see the Parent and Educator Resource Guide to Section 504, available on the U.S. Department of Education website at https://www2.ed.gov/about/offices/list/ocr/docs/504-resource-guide-201612.pdf.



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.

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

Please see <u>Full Prescribing Information</u> for DYANAVEL XR, including Boxed Warning regarding Abuse and Dependence, and Medication Guide.

Ready to get started? You've come to the right place.

Tris Pharma is here to help support you as you get your child started on DYANAVEL XR (amphetamine).

Save on co-pays. You may pay as little as \$25 for a prescription of DYANAVEL XR.



Ask your doctor for your own co-pay card. Card issue is subject to eligibility. Terms and Conditions apply.

Please see Full Prescribing Information and Medication Guides at www.quillivantxr.com and www.dyanavelxr.com.



Get a digital eCard, along with helpful refill reminders.

Simply text "TRIS" to TRIS4U (874748).*

*Mobile Terms and Conditions: coupon.trisadhd.com/terms Message and Data rates may apply.

Additional help and support.

Centers for Disease Control and Prevention (CDC) Attention-Deficit / Hyperactivity Disorder (ADHD) cdc.gov/ncbddd/adhd/

National Institute of Mental Health nimh.nih.gov/health/topics/attention-deficithyperactivity-disorder-adhd

Children and Adults with Attention-Deficit / Hyperactivity Disorder (CHADD) chadd.org

HealthyChildren.org from the American Academy of Pediatrics

healthychildren.org

The Attention Deficit Disorder Association (ADDA) add.org



Tris is dedicated to ADHD treatment

Tris Pharma has a family of proven treatment options for ADHD in patients aged 6 years old and above.

Why the need for options? No two children are alike. Why should their medicine, or their dose, be the same? Tris products cover both main types of ADHD medicines methylphenidate as well as amphetamine. And the good news is that about 85% of patients with ADHD respond to one or the other.

Innovative LiquiXR® technology.

The Tris Pharma family offers the treatment options that physicians and parents need. All of them are based on the unique and innovative LiquiXR extended-release technology, designed to help control your child's symptoms throughout their day.



THE TRIS PHARMA FAMILY OF ADHD TREATMENTS.

LIQUID





Please see Full Prescribing Information and Medication Guide at www.quillivantxr.com

TABLETS



Please see Full Prescribing Information and Medication Guide at www.dyanavelxr.com/tablet



Please see Full Prescribing Information and Medication Guide at www.quillichewer.com

