

WHAT IS QUILLIVANT XR?

Quillivant XR (methylphenidate hydrochloride) is a central nervous system stimulant prescription medicine. **Quillivant XR is a liquid medicine** that you take by mouth.

Quillivant XR is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). **Quillivant XR** may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

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

IMPORTANT SAFETY INFORMATION

Quillivant XR is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Quillivant XR in a safe place to prevent misuse and abuse. Selling or giving away Quillivant XR may harm others and is against the law. Tell your doctor if you or your child have (or have a family history of) 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 situations	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 their turn
Has a hard time listening, even when spoken to directly	Constantly on the go, as if driven by motor	Intrudes on other people's activities or conversations
Loses things	Talks nonstop	
	Seems unable to play or to occupy themselves quietly	

(This is not a complete list of symptoms.)

IMPORTANT SAFETY INFORMATION (cont'd)

Quillivant XR (methylphenidate hydrochloride) should not be taken if you or your child are allergic to methylphenidate hydrochloride, or any of the ingredients in Quillivant XR, or are taking or have taken within the past 14 days an antidepression 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. 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)

The following have been reported with the use of methylphenidate hydrochloride and other stimulant medicines:

- Heart-related problems:
 - Sudden death in patients who have heart problems or heart defects
 - Stroke and heart attack in adults
 - Increased blood pressure and heart rate
 - Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with Quillivant XR (methylphenidate hydrochloride)
- Mental (psychiatric) problems:
 - New or worse behavior and thought problems
 - New or worse bipolar illness
 - May cause new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms
- Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon):
 - Fingers or toes may feel numb, cool, painful, or may change color from pale, to blue, to red

Ask your doctor about Quillivant XR.

Quillivant XR (methylphenidate hydrochloride) is a prescription medicine that may help increase attention and decrease impulsiveness and hyperactivity in people 6 years and older with ADHD.

As a concerned parent, you should know that the use of methylphenidate products in treating children with ADHD has been well established. The methylphenidate Quillivant 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).

Why a liquid?

Every child is different. Doctors usually start by prescribing a low dose of a stimulant medicine. Quillivant XR is a liquid medication that allows your doctor to start low and adjust the dose up or down, slowly, in small amounts, to find the dose that helps improve your child's ADHD symptoms while minimizing side effects.

Once-a-day Quillivant 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)

Call your healthcare provider right away if you or your child have any:

- · Heart-related symptoms such as chest pain, shortness of breath, or fainting
- · New or worsening mental (psychiatric) symptoms or new manic symptoms
- Signs of unexplained wounds appearing on fingers or toes while taking Quillivant XR

Quillivant XR may not be right for you or your child. Tell your healthcare provider if:

- You or your child have, or have a family history of, heart problems, heart defects, or high blood pressure
- You or your child have mental problems, including psychosis (hearing voices, believing things that are not true, are suspicious), mania, bipolar illness, or depression, or a family history of suicide, bipolar illness, or depression
- You or your child have circulation problems in fingers and toes
- You are pregnant or plan to become pregnant. It is not known if Quillivant XR will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant
- You are breastfeeding or plan to breastfeed. Quillivant XR passes into your breast milk. You and your doctor should decide if you will take Quillivant XR or breastfeed

Helps control symptoms from morning through homework time.



Starts working rapidly

Morning can be a tough time for a child with ADHD. Quillivant XR (methylphenidate hydrochloride) has been proven to start working quickly—as early as 45 minutes.



Long lasting—to get your child through their day

In a laboratory classroom study, Quillivant XR was proven to keep working for up to 12 hours after taking it.*



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

Liquid Quillivant XR allows your health care professional to adjust the dose, up or down, weekly, in small amounts of 2 to 4 mL.

*In a clinical study of 45 children with ADHD aged 6 to 12 years performed in a laboratory classroom, Quillivant XR was found effective at reducing the symptoms of ADHD at all measured times (45 minutes, 2, 4 [primary endpoint], 8, 10, and 12 hours after taking) compared to a sugar pill.

IMPORTANT SAFETY INFORMATION (cont'd)

What should I avoid while taking Quillivant XR?

Quillivant XR should not be taken with MAOI medicines or if you stopped taking an MAOI in the last 14 days. Do not drink alcohol while taking Quillivant XR. This may cause a faster release of your methylphenidate dose.

What are the possible side effects of Quillivant XR?

Quillivant XR may cause serious side effects, including:

• See "What is the most important information I should know about Quillivant XR?" for information on reported heart and mental problems

Taking Quillivant XR.

Quillivant XR (methylphenidate hydrochloride) should be taken exactly as prescribed by your doctor. For step-by-step 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 Quillivant 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. Some of the most common side effects of Quillivant XR are: decreased appetite, trouble sleeping, nausea, vomiting, indigestion, stomach pain, weight loss. Others are anxiety, dizziness, irritability, mood swings, fast heart beat, and increased blood pressure.

These are not all the possible side effects of Quillivant XR. Please see the Important Safety Information on page 3 for additional details.

Questions for your child's doctor about Quillivant XR.

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

IMPORTANT SAFETY INFORMATION (cont'd)

Other serious side effects include:

- · Painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism seek medical help right away. Because priapism can cause long-lasting damage, it should be checked by a healthcare provider right away
- Slowing of growth (height and weight) in children

Common side effects include:

Stomach pain Mood swings Decreased appetite Trouble sleeping Weight loss Fast heart beat Increased blood Nausea Anxiety pressure

Vomiting Dizziness

Indigestion Irritability

These are not all the possible side effects of Quillivant XR.

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)

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

Please see <u>Full Prescribing Information</u> for Quillivant 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 Quillivant XR (methylphenidate hydrochloride).

Save on co-pays. You may pay as little as \$25 for a prescription of Quillivant 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.quillichewer.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-deficit-hyperactivity-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



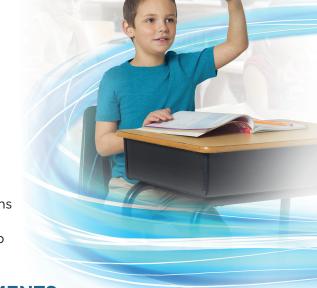
Tris is dedicated to ADHD treatment

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 and 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.dyanavelxr.com/liquid

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

