





WHAT IS QUILLICHEW ER?

QuilliChew ER (methylphenidate hydrochloride) is a central nervous system stimulant prescription medicine. **QuilliChew ER is a chewable tablet.**

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

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

IMPORTANT SAFETY INFORMATION

QuilliChew ER is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep QuilliChew ER in a safe place to prevent misuse and abuse. Selling or giving away QuilliChew ER 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	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	Runs, dashes around, or	
Makes careless mistakes	climbs in inappropriate	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)

QuilliChew ER (methylphenidate hydrochloride) should not be taken if you or your child are allergic to methylphenidate hydrochloride, or any of the ingredients in QuilliChew ER, 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 QuilliChew (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 QuilliChew ER.

QuilliChew ER (methylphenidate hydrochloride) is the first and only once-daily, extended-release chewable methylphenidate tablet for the treatment of ADHD in people 6 years old and above.

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

QuilliChew ER: When tablets are the preferred option for your child.

QuilliChew ER tablets use the innovative, proprietary **LiquiXR**® technology from Tris Pharma. Your child takes the prescribed dose of QuilliChew ER 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.

*QuilliChew ER was studied in a laboratory classroom setting in 90 children aged 6 to 12 years with a diagnosis of ADHD. Children taking QuilliChew ER showed improved attention and behavior at 45 minutes, 2, 4, and 8 hours after taking, when compared with those children who took sugar pills.



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 QuilliChew ER

QuilliChew ER 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 or your child have phenylketonuria (PKU). QuilliChew ER contains phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU or who are allergic to phenylalanine

An extended-release tablet that can be chewed or swallowed whole.





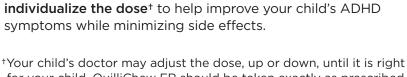


Proven efficacy



Customized dosing

Every child is different. Doctors usually start by prescribing a low dose of a stimulant medicine. QuilliChew ER (methylphenidate hydrochloride) tablets come in three strengths. This gives your child's doctor multiple options for dosing and dose adjustments. This allows the doctor to individualize the dose[†] to help improve your child's ADHD





for your child. QuilliChew ER should be taken exactly as prescribed.

IMPORTANT SAFETY INFORMATION (cont'd)

- · You are pregnant or plan to become pregnant. It is not known if QuilliChew ER 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. QuilliChew ER passes into your breast milk. You and your doctor should decide if you will take QuilliChew ER or breastfeed

What should I avoid while taking QuilliChew ER?

QuilliChew ER 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 QuilliChew ER. This may cause a faster release of your methylphenidate dose.

What are the possible side effects of QuilliChew ER?

QuilliChew ER may cause serious side effects, including:

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

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

Taking QuilliChew ER.

Be sure your child takes QuilliChew ER (methylphenidate hydrochloride) exactly as prescribed by your doctor. The doctor may adjust the dose until it is right for your child.

QuilliChew ER tablets are taken once each day, in the morning, with or without food.

The 20 mg and 30 mg QuilliChew ER chewable tablets are scored, so you can divide each tablet into equal halves to achieve the specific dose that is recommended by your child's doctor.

What should you expect when your child is starting QuilliChew ER?

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 QuilliChew ER 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 QuilliChew ER. Please see the Important Safety Information on page 3 for additional details.

Questions for your child's doctor about QuilliChew ER.

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

IMPORTANT SAFETY INFORMATION (cont'd)

Common side effects include:

Decreased appetite Stomach pain Mood swings

Trouble sleeping Weight loss Fast heart beat

Nausea Anxiety Increased blood

Vomiting Dizziness pressure

Indigestion Irritability

These are not all the possible side effects of QuilliChew ER.

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 QuilliChew ER, 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 QuilliChew ER (methylphenidate hydrochloride).

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



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 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.

TABLETS





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

LIQUID



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



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

