

Medication Guide

QUILLIVANT XR® (kwil-ə-vant\ (methylphenidate hydrochloride) for extended-release oral suspension CII

What is the most important information I should know about QUILLIVANT XR?

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 health care provider if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

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

1. 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**

Tell your health care provider if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your health care provider should check you or your child carefully for heart problems before starting QUILLIVANT XR.

Your health care provider should check your or your child's blood pressure and heart rate regularly during treatment with QUILLIVANT XR.

Call your health care provider right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking QUILLIVANT XR.

2. Mental (Psychiatric) problems:

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**
- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

Tell your health care provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your health care provider right away if you or your child have any new or worsening mental symptoms or problems while taking QUILLIVANT XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

3. Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]:

- Fingers or toes may feel numb, cool, painful
- Fingers or toes may change color from pale, to blue, to red

Tell your health care provider if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.

Call your health care provider right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking QUILLIVANT XR.

What is QUILLIVANT XR?

QUILLIVANT XR is a central nervous system stimulant prescription medicine.

QUILLIVANT XR is a liquid medicine that you take by mouth.

It 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.

Do not take QUILLIVANT XR if you or your child:

- are allergic to methylphenidate hydrochloride, or any of the ingredients in QUILLIVANT XR. See the end of this Medication Guide for a complete list of ingredients in QUILLIVANT XR.
- are taking or have taken within the past 14 days a type of anti-depression medicine called a monoamine oxidase inhibitor (MAOI).

QUILLIVANT XR may not be right for you or your child. Before starting QUILLIVANT XR tell your or your child's health care provider about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers and toes
- if you are pregnant or plan to become pregnant. It is not known if QUILLIVANT XR will harm your unborn baby. Talk to your health care provider if you are pregnant or plan to become pregnant.
 - There is a pregnancy registry for females who are exposed to ADHD medications during pregnancy. The purpose of the registry is to collect information about the health of females exposed to QUILLIVANT XR and their baby. If you or your child becomes pregnant during treatment with QUILLIVANT 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/>.
- if you are breastfeeding or plan to breast feed. QUILLIVANT XR passes into your breast milk. You and your doctor should decide if you will take QUILLIVANT XR or breast feed.

Tell your health care provider about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements. QUILLIVANT XR and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking QUILLIVANT XR.

Your health care provider will decide whether QUILLIVANT XR can be taken with other medicines.

Especially tell your health care provider if you or your child takes:

- anti-depression medicines including MAOIs

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your health care provider and pharmacist. **Do not start any new medicine while taking QUILLIVANT XR without talking to your health care provider first.**

How should QUILLIVANT XR be taken?

- **Read the step-by-step instructions for using QUILLIVANT XR extended-release suspension at the end of this Medication Guide.**

- Take QUILLIVANT XR exactly as prescribed. Your health care provider may adjust the dose, if needed, until it is right for you or your child. During dose adjustment, you or your child may still have ADHD symptoms.
- QUILLIVANT XR should be used with the oral dosing dispenser provided with the product. If the oral dosing dispenser is missing or not provided, please contact your pharmacist for a replacement.
- Check and make sure that the QUILLIVANT XR bottle contains liquid medicine. If QUILLIVANT XR is in powder form, do not use it. Return it to your pharmacist.
- Check and make sure that the bottle adapter was fully inserted into the bottle by the pharmacist. If the bottle adapter is not fully inserted, insert the adapter into the bottle.
- Take QUILLIVANT XR 1 time each day in the morning. QUILLIVANT XR is an extended-release suspension. It releases medicine into your body throughout the day.
- QUILLIVANT XR can be taken with or without food. Taking QUILLIVANT XR with food may shorten the time it takes for the medicine to start working.
- From time to time, your health care provider may stop QUILLIVANT XR treatment for a while to check ADHD symptoms.
- Your health care provider may do regular checks of the blood, heart, and blood pressure while taking QUILLIVANT XR.
- Children should have their height and weight checked often while taking QUILLIVANT XR. QUILLIVANT XR treatment may be stopped if a problem is found during these check-ups.
- In case of poisoning call your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.
- If a dose is missed, you or your child should talk to your health care provider about dosing.

What should I avoid while taking QUILLIVANT XR?

- QUILLIVANT XR should not be taken with MAOI medicines. Do not start taking QUILLIVANT XR 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.

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 health care provider right away.**
- slowing of growth (height and weight) in children

The most common side effects of QUILLIVANT XR include:

- decreased appetite
- trouble sleeping
- nausea
- vomiting
- indigestion
- stomach pain
- weight loss
- anxiety
- dizziness
- irritability
- mood swings
- fast heart beat
- increased blood pressure

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

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

How should I store QUILLIVANT XR?

- Store QUILLIVANT XR in a safe place at 59°F to 86°F (15°C to 30°C).
- **Keep QUILLIVANT XR and all medicines out of the reach of children.**

General information about the safe and effective use of QUILLIVANT XR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use QUILLIVANT XR for a condition for which it was not prescribed. Do not give QUILLIVANT XR to other people, even if they have the same condition. It may harm them.

You can ask your pharmacist or health care provider for information about QUILLIVANT XR that was written for health care professionals.

What are the ingredients in QUILLIVANT XR?

Active Ingredient: methylphenidate hydrochloride

Inactive Ingredients: sodium polystyrene sulfonate, povidone, triacetin, polyvinyl acetate, sucrose, anhydrous trisodium citrate, anhydrous citric acid, sodium benzoate, sucralose, poloxamer 188, corn starch, xanthan gum, talc, banana flavor, and silicon dioxide.

For more information, go to www.quillivantxr.com or call (732)-940-0358.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This product's label may have been updated. For current full prescribing information, please visit www.trispharma.com.

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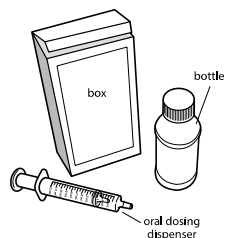
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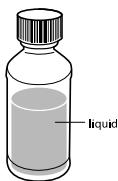
Instructions for Use
QUILLIVANT XR® (\kwil-ə-vant\
(methylphenidate hydrochloride)
for extended-release oral suspension CII

Read this Instructions for Use before using QUILLIVANT XR and each time you get a refill. There may be new information. This leaflet does not take the place of talking with the health care provider about your or your child's medical condition or treatment.

Step 1. Remove the QUILLIVANT XR bottle and oral dosing dispenser from the box (**See Figure A**). If the oral dosing dispenser is missing or not provided, please contact your pharmacist for a replacement.



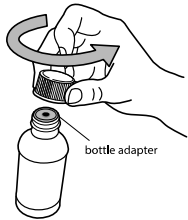
Step 2. Check and make sure that the QUILLIVANT XR bottle contains liquid medicine (**See Figure B**). If QUILLIVANT XR is still in powder form, **do not use it**. Return it to your pharmacist.



Step 3. Shake the bottle well (up and down) for at least 10 seconds before each use (**See Figure C**).

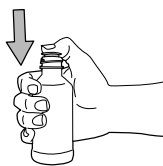
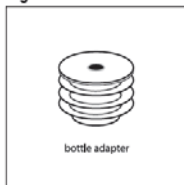


Step 4. Uncap the bottle and check that the bottle adapter has been fully inserted into the bottle (**See Figure D**).



Step 4 (continued). If bottle adapter (**See Figure E**) has not been inserted by the pharmacist into the bottle, insert adapter into the bottle as shown (**See Figure E and Figure F**).

Figure E

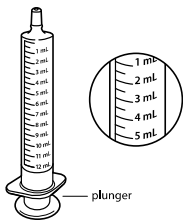


After the bottle adapter has been fully inserted into the bottle (**See Figure G**), it should not be removed. If the bottle adapter has not been inserted and is missing from the box, contact your pharmacist.

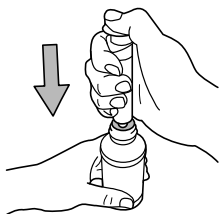
The bottle adapter must be fully inserted and should be even with the mouth of the bottle and must remain in place to allow the child resistant cap to work the right way.



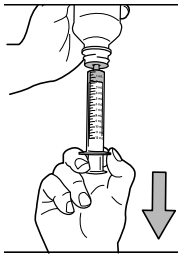
Step 5. Check the QUILLIVANT XR dose in milliliters (mL) as prescribed by your health care provider. Locate this number on the oral dosing dispenser (See **Figure H**).



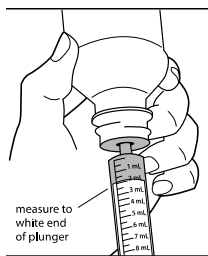
Step 6. Insert tip of the oral dosing dispenser into the upright bottle and push the plunger all the way down (See **Figure I**).



Step 7. With the oral dosing dispenser in place, turn the bottle upside down. Pull the plunger to the number of mL you need (the amount of liquid medicine in **Step 5** – See **Figure J**).



Step 7 (continued). Measure the number of mL of medicine from the white end of the plunger (See **Figure K**).



Step 8. Remove the oral dosing dispenser from the bottle adapter.

Step 9. Slowly squirt QUILLIVANT XR directly into your or your child's mouth (See **Figure L**).



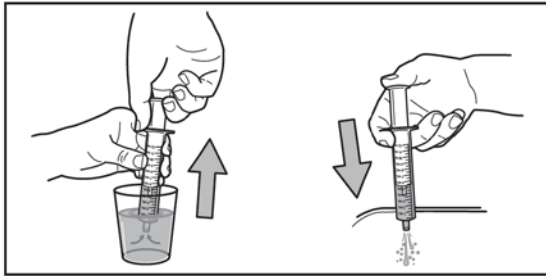
Step 10. Cap the bottle tightly. Store the bottle upright at 59°F to 86°F (15°C to 30°C) (See **Figure M**).

Figure M



Step 11. Clean the oral dosing dispenser after each use by placing in the dishwasher, or by rinsing with tap water (**See Figure N**).

Figure N



These Instructions for Use have been approved by the U.S. Food and Drug Administration. This product's label may have been updated. For current full prescribing information, please visit www.trispharma.com.

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