QUILLIVANT XR®

for extended-release oral suspension, CII

HIGHLIGHTS OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE
QUILLIVANT XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) [see Clinical Studies (14)].

CONTRAINDICATIONS
QUILLIVANT XR is contraindicated during treatment with monoamine oxidase inhibitors (MAOIs), and also within 14 days of discontinuing treatment with a MAOI, and within 14 days after discontinuation of QUILLIVANT XR. Concurrent use of QUILLIVANT XR with a MAOI is contraindicated, and use of a MAOI within the preceding 14 days is contraindicated [see Warnings and Precautions (5.2)].

WARNING: ABUSE AND DEPENDENCE

Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy. Maintain careful record of the quantity taken for each patient, and destroy any unused quantities when treatment is completed [see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2, 9.3)].

SIDE EFFECTS

Patients should be advised to avoid alcohol while taking QUILLIVANT XR [see Clinical Pharmacology (12.3)].

ADDENDUM

Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including QUILLIVANT XR. Patients treated with methylphenidate for extended periods may exhibit growth retardation, although this effect is not seen in all treated patients [see Warnings and Precautions (5.2)].

CLINICAL STUDIES

The efficacy of QUILLIVANT XR was evaluated in a laboratory classroom study conducted in 45 pediatric patients (ages 6 to 12 years) were affect lability, excoriation, initial insomnia, tic, decreased appetite, nausea, abdominal pain, dyspepsia, dry mouth, vomiting, insomnia, anxiety, nervousness, restlessness, affect lability. These findings, however, are not statistically significant.

QUANTITATIVE STRUCTURAL ANALYSIS

Table: Post-dose Release kinetic parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>QUILLIVANT XR</th>
<th>Reference methylphenidate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum plasma concentration</td>
<td>1000 ng/mL</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>Area under the curve</td>
<td>10,000 ng·h/mL</td>
<td>5000 ng·h/mL</td>
</tr>
<tr>
<td>Time to peak concentration</td>
<td>2 hours</td>
<td>1 hour</td>
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</tbody>
</table>

COMMENTS

QUILLIVANT XR Oral Suspension is a formulation of methylphenidate that is intended for once daily oral administration. QUILLIVANT XR contains approximately 20% immediate-release methylphenidate and 80% extended-release methylphenidate. After reconstitution, QUILLIVANT XR is available in a 25 mg per 5 mL (5 mg per 1 mL) dosage form.

QUANTITATIVE STRUCTURAL ANALYSIS

Methylphenidate is a racemic mixture comprised of the d- and l-isomers. The d-isomer is more pharmacologically active than the l-isomer. Methylphenidate is a central nervous system (CNS) stimulant.

PHARMACOKINETICS

Methylphenidate is rapidly absorbed following oral administration. It is extensively metabolized to active metabolites, including the dihydroxylated metabolite (PPAA), which is responsible for the therapeutic effects of methylphenidate.

REFERENCES


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

QUILLIVANT XR® is a liquid medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Before starting QUILLIVANT XR tell your or your child’s health care provider about all health conditions (or a family history) including:

• heart problems, heart defects, high blood pressure
• major side effects including psychosis, mood, liver, kidney, or depression
• problems such as chest pain, shortness of breath, or fainting while taking QUILLIVANT XR.

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

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

• breath, or fainting while taking 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 fast heart rate.

Your health care provider may do regular checks of the blood, blood pressure, and heart rate during regular check-ups.

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

Do not start taking QUILLIVANT XR if you or your child have any of these problems, such as chest pain, shortness of breath, or fainting while taking QUILLIVANT XR.

Tell your health care provider about all the medicines you or your child take including prescription and over-the-counter medicines, vitamin, and herbal supplements. QUILLIVANT XR and some medicines may interact with each other and cause serious side effects. Sometimes the cause 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.

Do not start any new medicine while taking QUILLIVANT XR without talking to your health care provider first.

What should I avoid while taking QUILLIVANT XR®?

• Fingers or toes may change color from pale, to blue, to red.

• You should be even with the mouth of the bottle.

• Check and make sure that the bottle adapter was fully inserted into the bottle.

• Check and make sure that the QUILLIVANT XR bottle contains liquid medicines, sodium polystyrene sulfonate, povidone, and some medicines may interact with each other and cause serious side effects. Sometimes the cause 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.

Do not start any new medicine while taking QUILLIVANT XR without talking to your health care provider first.

How should I take QUILLIVANT XR®?

• QUILLIVANT XR should not be taken with MAOI medicines. Do not take MAOI medicines for at least 14 days after ending QUILLIVANT XR treatment.

• If a problem is found during these check-ups.

• Take QUILLIVANT XR 1 time each day in the morning.

• Check and make sure that the dispense tip was inserted into the bottle (Figure G). The dispense tip should be even with the mouth of the bottle (Figure H).

• Slowly squirt QUILLIVANT XR directly into your or your child’s mouth (Figure I).

• Squeeze the bottle in your hand over your mouth or the child’s mouth (Figure J).

• Slowly squeeze the pump of the oral dosing dispenser into the child’s mouth (Figure K).

• Squeeze the bottle in your hand over your mouth or the child’s mouth (Figure L).

• The bottle adapter must be fully inserted into the bottle (Figure M).

• After the bottle adapter has been fully inserted into the bottle (Figure N).

• The bottle adapter should be even with the bottle and the medicine will not be mixed. If the bottle adapter is not inserted into the bottle, contact your pharmacist.

• The bottle adapter must be fully inserted and should be even with the mouth of the bottle and the medicine will not be mixed. If the bottle adapter is not inserted into the bottle, contact your pharmacist.

• Slowly insert the cool dosing dispenser into the upright bottle and push the plunger all the way down (Figure O).

• The bottle adapter should be even with the bottle and the medicine will not be mixed. If the bottle adapter is not inserted into the bottle, contact your pharmacist.

• Slowly insert QUILLIVANT XR directly into your or your child’s mouth (Figure P).

• Slowly insert the cool dosing dispenser into the upright bottle and push the plunger all the way down (Figure Q).

• Slowly insert the cool dosing dispenser into the upright bottle and push the plunger all the way down (Figure R).