2.2 General Dosing Information

- For patients 6 years and above, the recommended starting dose is 20 mg given orally as needed.

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3.2 PharMacia Methylphenidate HCl Tablets

- The recommended starting dose is 20 mg per day. Daily dosage above 60 mg is not recommended. (2.1)

5.5 Priapism

- Priapism, which is defined as an excessively sustained or frequent unwanted tumescence of the penis, has been reported with methylphenidate products. Because the risk of Priapism is greater with extended-release formulations, it is recommended to use the 10 mg tablets for doses up to 20 mg or the 20 mg tablets for doses above 20 mg per day.

6.1 Clinical Trials Experience with QuilliChew ER in Children with ADHD

- The following adverse reactions have been identified during post-marketing surveillance of methylphenidate products in children with ADHD. These reactions have been voluntarily reported from a potentially large number of post-marketing adverse event reports and individual cases. They include: aggressive acts, including violence, attentional difficulties, new behavior problem or worsening of old behavior problems, hostility, irritability, mood fluctuation, noncompliance, oppositional defiant disorder, psychomotor agitation, psychophysiological disturbances, problem behavior, suicidal ideation, and suicide attempt.

6.2 Laboratory Tests

- Laboratory tests have shown that the use of methylphenidate may cause a slight decrease in weight and growth in some children. A decrease in appetite, weight, and growth in children and adolescents has been reported in clinical trials and post-marketing surveillance studies. This decrease in growth rate is usually not clinically significant. However, a decrease in growth rate can be clinically significant in children and adolescents who are already at or near their target height or weight and who show signs of undernutrition. It is important to monitor height and weight at appropriate intervals in these patients.

7.7 Safety of Patients with Pheochromocytoma

- Methylphenidate should be used with caution in patients with pheochromocytoma, as it may exacerbate the symptoms of this disease. Methylphenidate should be discontinued if the signs and symptoms of pheochromocytoma worsen or if the patient develops new or worsening symptoms.

9.1 Description

- QuilliChew ER is a centrally acting stimulant medication. It is available as a 10 mg extended-release chewable tablet, a 20 mg extended-release chewable tablet, and a 40 mg extended-release chewable tablet.

10.1 Overview

- Consult with a Cardiologist if considered necessary for the evaluation of cardiovascular risk. Methylphenidate products may be used in patients with a history of cardiovascular disease, including QuilliChew ER. A careful history and physical examination should be performed in patients with hypertension or cardiovascular disease, and the patient should be monitored for signs and symptoms of cardiovascular disease. Methylphenidate products may also be used in patients with a history of stroke or myocardial infarction. The patient should be monitored for signs and symptoms of cardiovascular disease.

11.1 Description

- QuilliChew ER is a centrally acting stimulant medication. It is available as a 10 mg extended-release chewable tablet, a 20 mg extended-release chewable tablet, and a 40 mg extended-release chewable tablet.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

- Methylphenidate is a stimulant medication and may have teratogenic effects in pregnant women. It is not known if the drug crosses the placenta. Therefore, it is recommended that pregnant women and women of reproductive potential use other forms of contraception while taking methylphenidate products.

14.3 Pharmacokinetics

- Methylphenidate undergoes hepatic metabolism and is excreted primarily in urine. After oral administration, methylphenidate is rapidly absorbed from the gastrointestinal tract and is distributed throughout the body. The drug is extensively metabolized by the liver and undergoes conjugation with glucuronic acid. Methylphenidate is metabolized primarily to dextromethorphan and dextrorphan.

14.4 Metabolism

- Methylphenidate is metabolized primarily to dextromethorphan and dextrorphan.

15.1 Description

- Methylphenidate is a centrally acting stimulant medication. It is available as a 10 mg extended-release chewable tablet, a 20 mg extended-release chewable tablet, and a 40 mg extended-release chewable tablet.
Do not take QuilliChew ER if you or your child:

- are allergic to methylphenidate hydrochloride, or any of the ingredients in QuilliChew ER. See the end of this Medication Guide for a complete list of ingredients in QuilliChew ER.
- have taken or have taken within the past 14 days a type of anti-depressant medicine called a monoamine oxidase inhibitor (MAOI). QuilliChew ER may not be right for you or your child. Before starting QuilliChew ER tell your or your child’s health care provider about all health conditions (or a 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

QuilliChew ER extended-release chewable tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU or who are allergic to phenylalanine.
- if you are pregnant or plan to become pregnant. It is not known if QuilliChew ER will harm your unborn baby. Talk to your health care provider if you are pregnant or plan to become pregnant.
- if you are breastfeeding or plan to breast feed. QuilliChew ER goes into your breast milk. You and your doctor should decide if you will take QuilliChew ER or breastfeed.

Tell your health care provider about all of the medicines that you take including prescription and non-prescription medicines, vitamins, and herbal supplements. QuilliChew ER and some medicines may interact with each other. Sometimes the doses of other medicines will need to be adjusted while taking QuilliChew ER.

Your health care provider will decide whether QuilliChew ER can be taken with other medicines.

- especially tell the health care provider if you or your child:
  - have taken or have taken within the past 14 days a type of anti-depressant medicine called a monoamine oxidase inhibitor (MAOI) or are taking or have taken within the past 14 days a type of anti-depressant medicine called a monoamine oxidase inhibitor (MAOI). QuilliChew ER may not be right for you or your child. Before starting QuilliChew ER tell your or your child’s health care provider about all health conditions (or a 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
  -Priapism

Other serious side effects include:

- painful and prolonged erections

Some medicines are not safe to use with QuilliChew ER.

How can I Store QuilliChew ER?

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 health care provider if you or your child have or have had a family history of abuse or addiction to substances that are addictive, 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 children who have heart problems or heart defects
- stroke and heart attack in adults

Tell your health care provider if you or your child have or have had 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 QuilliChew ER.

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

Tell 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 QuilliChew ER.

2. Mental problems including psychosis, mania, bipolar illness, or depression

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychiatric 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.

3. Circulation problems in fingers and toes (Peripheral vasculopathy, including Raynaud’s phenomenon)

- Fingers or toes may feel numb, cold, painful
- Fingers or toes may change color

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

4. Call your health care provider right away if you or your child:

- develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease (see Warnings and Precautions [5.4]).
- have any new or worsening mental symptoms or problems including psychosis, mania, bipolar illness, or depression
- painful and prolonged erections (priapism)
- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers and toes

Special considerations for use of QuilliChew ER by females

- Pregnancy — Tell your health care provider if you are pregnant or plan to become pregnant. It is not known if QuilliChew ER is safe and effective in children under 6 years of age.

What is QuilliChew ER?

QuilliChew ER is a central nervous system stimulant prescription medicine for oral use. It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 to 17 years of age. 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.

The most common side effects of QuilliChew ER include:

- decreased appetite
- mood swings
- anxiety
- weight loss
- irritability

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

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 QuilliChew ER?

- Store QuilliChew ER in a safe place at 68°F to 77°F (20°C to 25°C). Do not use if this label has expired.
- Keep QuilliChew ER and all medicines out of the reach of children.

General information about the safety and effective use of QuilliChew ER

QuilliChew ER is a central nervous system stimulant prescription medicine for oral use. It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 to 17 years of age. 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.

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