

## MEDICATION GUIDE

### Methylphenidate Hydrochloride Chewable Tablets

2.5 mg, 5 mg, and 10 mg

Read the Medication Guide that comes with Methylphenidate Hydrochloride Chewable Tablets before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with Methylphenidate Hydrochloride Chewable Tablets.

#### What is the most important information I should know about Methylphenidate Hydrochloride Chewable Tablets?

The following have been reported with use of methylphenidate HCl 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 doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting Methylphenidate Hydrochloride Chewable Tablets.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with Methylphenidate Hydrochloride Chewable Tablets.

**Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Methylphenidate Hydrochloride Chewable Tablets.**

##### 2. Mental (Psychiatric) problems:

All Patients

- new or worse behavior and thought problems
- new or worse bipolar illness
- new or worse aggressive behavior or hostility

Children and Teenagers

- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

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

**Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking Methylphenidate Hydrochloride Chewable Tablets, 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, and/or may change color from pale, to blue, to red.

- Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.
- Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Methylphenidate Hydrochloride Chewable Tablets.

#### What Are Methylphenidate Hydrochloride Chewable Tablets?

Methylphenidate Hydrochloride Chewable Tablets are a central nervous system stimulant prescription medicine. Methylphenidate Hydrochloride Chewable Tablets are tablets that are made to be chewed and swallowed. They are used for the treatment of Attention Deficit and Hyperactivity Disorder (ADHD). Methylphenidate Hydrochloride Chewable Tablets may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Methylphenidate Hydrochloride Chewable Tablets should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Methylphenidate Hydrochloride Chewable Tablets are also used in the treatment of a sleep disorder called narcolepsy.

**Methylphenidate Hydrochloride Chewable Tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate Hydrochloride Chewable Tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate Hydrochloride Chewable Tablets 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.

#### Who should not take Methylphenidate Hydrochloride Chewable Tablets?

**Methylphenidate Hydrochloride Chewable Tablets should not be taken if you or your child:**

- are very anxious, tense, or agitated
- have an eye problem called glaucoma
- have tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are hard to control repeated movements or sounds.
- are taking or have taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI.
- are allergic to anything in Methylphenidate Hydrochloride Chewable Tablets. See the end

of this Medication Guide for a complete list of ingredients.

Methylphenidate Hydrochloride Chewable Tablets should not be used in children less than 6 years old because it has not been studied in this age group.

**Methylphenidate Hydrochloride Chewable Tablets may not be right for you or your child. Before starting Methylphenidate Hydrochloride Chewable Tablets tell your or your child's doctor 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
- tics or Tourette's syndrome
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers and toes

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

#### Can Methylphenidate Hydrochloride Chewable Tablets be taken with other medicines?

**Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements.**

Methylphenidate Hydrochloride Chewable Tablets 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 Methylphenidate Hydrochloride Chewable Tablets.

Your doctor will decide whether Methylphenidate Hydrochloride Chewable Tablets can be taken with other medicines.

**Especially tell your doctor if you or your child takes:**

- anti-depression medicines including MAOIs
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- cold or allergy medicines that contain decongestants

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

**Do not start any new medicine while taking Methylphenidate Hydrochloride Chewable Tablets without talking to your doctor first.**

#### How should Methylphenidate Hydrochloride Chewable Tablets be taken?

- Take Methylphenidate Hydrochloride Chewable Tablets exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Methylphenidate Hydrochloride Chewable Tablets are usually taken 2 to 3 times a day.

- Take Methylphenidate Hydrochloride Chewable Tablets 30 to 45 minutes before a meal.

**• Chew Methylphenidate Hydrochloride Chewable Tablets well and swallow with at least 8 ounces (a full glass) of water or other liquid. Methylphenidate Hydrochloride Chewable Tablets can swell and cause choking if enough liquid is not taken with them. Get emergency medical care if you have chest pain, vomiting, or trouble swallowing, or breathing after taking a Methylphenidate Hydrochloride Chewable Tablet.**

- From time to time, your doctor may stop Methylphenidate Hydrochloride Chewable Tablets treatment for awhile to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Methylphenidate Hydrochloride Chewable Tablets. Children should have their height and weight checked often while taking Methylphenidate Hydrochloride Chewable Tablets. Methylphenidate Hydrochloride Chewable Tablets treatment may be stopped if a problem is found during these check-ups.
- If you or your child takes too much Methylphenidate Hydrochloride Chewable Tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.

#### What are possible side effects of Methylphenidate Hydrochloride Chewable Tablets?

See "What is the most important information I should know about Methylphenidate Hydrochloride Chewable Tablets?" for information on reported heart and mental problems.

##### Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision
- Painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.

##### Common side effects include:

- nervousness
- trouble sleeping
- headache
- stomach ache
- fast heart beat
- nausea
- decreased appetite
- dizziness
- weight loss

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

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

#### How should I store Methylphenidate Hydrochloride Chewable Tablets?

- Store Methylphenidate Hydrochloride Chewable Tablets in a safe place at room temperature, 68° to 77°F (20° to 25°C). Protect from moisture.
- Keep Methylphenidate Hydrochloride Chewable Tablets and all medicines out of the reach of children.

#### General information about Methylphenidate Hydrochloride Chewable Tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Methylphenidate Hydrochloride Chewable Tablets for a condition for which it was not prescribed. Do not give Methylphenidate Hydrochloride Chewable Tablets to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Methylphenidate Hydrochloride Chewable Tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Methylphenidate Hydrochloride Chewable Tablets that was written for healthcare professionals.

#### What are the ingredients in Methylphenidate Hydrochloride Chewable Tablets?

**CAUTION PHENYLKETONURICS: Methylphenidate Hydrochloride Chewable Tablets contain phenylalanine.**

**Active Ingredient:** methylphenidate hydrochloride USP

**Inactive Ingredients:** aspartame, maltose, microcrystalline cellulose, grape flavor, pre-gelatinized starch, phosphoric acid, and stearic acid.

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

Manufactured by:  
Novel Laboratories Inc.  
400 Campus Drive,  
Somerset, NJ 08873  
USA

Manufactured for:  
GAVIS Pharmaceuticals, LLC  
Somerset, NJ 08873

PI5700000202  
Iss. 12/2015