Methylenidate Hydrochloride Extended-Release Tablets CII
(methyl’‘fe’’ date)

Read the Medication Guide that comes with methylphenidate hydrochloride extended-release 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 with your doctor about your child’s treatment with methylphenidate hydrochloride extended-release tablets.

What is the most important information I should know about methylphenidate hydrochloride extended-release tablets?

The following have been reported with USE: Methylphenidate HCl and other stimulant

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
   • heart problems, heart defects, high blood pressure, or a family history of these problems

Your doctor should check you or your child regularly for heart problems before starting methylphenidate hydrochloride extended-release tablets.

Your doctor should check your or your child’s blood pressure and heart rate regularly during treatment with methylphenidate hydrochloride extended-release 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.

2. Mental (Psychiatric) problems

a. Patients
   • new or worse behavior and thought problems
   • new or worse bipolar illness
   • new or worse aggressive behavior or hostility

b. Children and Teenagers
   • new psychotic symptoms (such as hearing things or seeing things that are not there or not true) or new or worsened mental symptoms or problems while taking methylphenidate hydrochloride extended-release tablets.

Call your doctor right away if you or your child has any new or worsening mental symptoms or problems while taking methylphenidate hydrochloride extended-release tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

3. Painful and prolonged erections (priapism)

Prolonged and painful erections (priapism) have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away.

4. Circulation problems in fingers and toes

Peripheral vasospasm, including Raynaud’s phenomenon

• fingers or toes may feel numb, cold, painful

• fingers or toes may turn white or blue

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

Can methylphenidate hydrochloride extended-release tablets be used with other medicines?

Tell your doctor about all the medicines that you or your child takes including prescription and nonprescription medicines, vitamins, and herbal supplements. Methylphenidate hydrochloride extended-release 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 extended-release tablets.

Your doctor will decide whether methylphenidate hydrochloride extended-release tablets can be taken with other medicines.

Especially tell your doctor if you or your child takes:

• antidepressant medicines including MAOIs
• other 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 or pharmacist when you get a refill.

Do not start any new medicine while taking methylphenidate hydrochloride extended-release tablets without talking to your doctor first.

How should methylphenidate hydrochloride extended-release tablets be taken?

For children age 6 and older, adult, and adolescent

Take methylphenidate hydrochloride extended-release tablets in the morning and evening for continuous 12 hour coverage. Do not split, chew, or crush methylphenidate hydrochloride extended-release tablets. Methylphenidate hydrochloride extended-release tablets can be swallowed whole before meals or at bedtime. They contain methylphenidate HCl, an immediate-release form of methylphenidate HCl. They also contain inactive ingredients such as lactose, microcrystalline cellulose, magnesium stearate, and crospovidone.

Methylphenidate hydrochloride extended-release tablets should be stored at room temperature 15-30°C (59-86°F) unless otherwise specified.

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