

METHYLPHENIDATE-TEVA XR

methylphenidate hydrochloride

Consumer Medicine Information

This leaflet provides important information about using METHYLPHENIDATE-TEVA XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using METHYLPHENIDATE-TEVA XR.**

Where to find information in this leaflet:

1. Why am I using METHYLPHENIDATE-TEVA XR?
2. What should I know before I use METHYLPHENIDATE-TEVA XR?
3. What if I am taking other medicines?
4. How do I use METHYLPHENIDATE-TEVA XR?
5. What should I know while using METHYLPHENIDATE-TEVA XR?
6. Are there any side effects?
7. Product details

1. Why am I using METHYLPHENIDATE-TEVA XR?

METHYLPHENIDATE-TEVA XR contains the active ingredient methylphenidate hydrochloride.

METHYLPHENIDATE-TEVA XR is a stimulant that increases attention and decreases impulsiveness and hyperactivity in patients with Attention Deficit Hyperactivity Disorder (ADHD).

METHYLPHENIDATE-TEVA XR is used to treat ADHD.

METHYLPHENIDATE-TEVA XR is part of a comprehensive treatment program which usually includes psychological, educational and social therapy.

METHYLPHENIDATE-TEVA XR should be used as part of a total treatment program for ADHD that may include counselling or other therapies.

2. What should I know before I use METHYLPHENIDATE-TEVA XR?

Warnings

Do not use METHYLPHENIDATE-TEVA XR if:

- You are allergic to methylphenidate hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- The packaging is torn or shows signs of tampering.

Symptoms of an allergic reaction may include: rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body.

Do not take METHYLPHENIDATE-TEVA XR if you/your child have any of the following medical conditions:

- glaucoma (increased pressure in the eye) which is poorly controlled
- overactive thyroid gland
- heart problems, including severe angina (chest pain), irregular heartbeat, heart muscle disease, high blood pressure (untreated or not under control)

- severe depression, anorexia nervosa, suicidal tendency or other mental illness
- pheochromocytoma (a tumour of the adrenal gland)
- have a history of drug or alcohol abuse
- currently taking or have taken a monoamine oxidase (MAO) inhibitor, medicines used to treat major depression (eg. phenelzine, tranylcypromine) or medicines used in Parkinson's disease (eg. selegiline) within the last 14 days

Check with your doctor if you:

- have any other medical conditions
 - are/is or have/has been alcohol or drug dependent
 - have/has seizures or fits
 - have/has heart problems
 - Heart-related problems including sudden death in patients who have heart problems or heart defects, stroke and heart attack in adults and increased blood pressure and heart rate have been reported with the use of methylphenidate, the active ingredient in METHYLPHENIDATE-TEVA XR.
 - have / had thoughts about suicide or attempted suicide
 - have/has high blood pressure
 - have/has aggressive behaviour or hostility
 - have/has a narrowing or blockage in your digestive tract (stomach, small or large intestine)
 - have tics (movements or sounds you cannot control) or Tourette's syndrome, or a family history of these conditions
 - have/has a problem with the blood vessels in your brain (such as an aneurysm)
 - have/has eye problems, such as increased pressure in the eye, a condition called "glaucoma" or long-sightedness (difficulty seeing near objects)
 - have/has liver or kidney problems
 - have/has mental problems including psychosis, mania, bipolar illness, or depression

Mental (psychiatric) problems may develop or get worse, including behaviour and thought problems, bipolar illness, aggressive behaviour or hostility.

Your doctor may need to adjust the dose or adapt your treatment if you/your child have any of these conditions.

If you have not told your doctor or pharmacist about any of the above, tell them before you/your child start taking METHYLPHENIDATE-TEVA XR.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in METHYLPHENIDATE-TEVA XR passes into breast milk and there is a possibility that your baby may be affected. Your doctor can

discuss with you the risks and benefits involved.