

MEDICATION GUIDE
JORNAY PM (JOR-nay)
(methylphenidate hydrochloride)
extended-release capsules, CII

What is the most important information I should know about JORNAY PM?

JORNAY PM may cause serious side effects, including:

Abuse, misuse, and addiction. JORNAY PM has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of JORNAY PM, other methylphenidate containing medicines, and amphetamine containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of JORNAY PM or when it is used in ways that are not approved, such as snorting or injection.

- Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with JORNAY PM and will monitor you or your child during treatment.
- JORNAY PM may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
- Do not give JORNAY PM to anyone else. See **“What is JORNAY PM?”** for more information.
- Keep JORNAY PM in a safe place and properly dispose of unused medicine. See **“How should I store JORNAY PM?”** for more information.
- Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease.

Your healthcare provider should check you or your child carefully for heart problems before starting JORNAY PM. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider right away or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with JORNAY PM.

- **Increased blood pressure and heart rate.**

Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with JORNAY PM.

- **Mental (psychiatric) problems, including:**

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms

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

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems during treatment with JORNAY PM, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is JORNAY PM?

JORNAY PM is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. JORNAY PM may help increase attention and decrease impulsiveness and hyperactivity in people 6 years of age and older with ADHD.

It is not known if JORNAY PM is safe and effective in children under 6 years of age.

JORNAY PM is a federally controlled substance (CII) because it contains methylphenidate that can be a target for people who abuse prescription medicines or street drugs. Keep JORNAY PM in a safe place to protect it from theft. Never give your JORNAY PM to anyone else, because it may cause death or harm them. Selling or giving away JORNAY PM may harm others, and is against the law.

Who should not take JORNAY PM?

Do not take JORNAY PM if you or your child is:

- allergic to methylphenidate hydrochloride, or any of the ingredients in JORNAY PM. See the end of this Medication Guide for a complete list of ingredients in JORNAY PM.
- taking or has taken within the last 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

Before taking JORNAY PM, tell your or your child's healthcare provider about all medical conditions, including if you or your child:

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers or toes
- have eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness)
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- are pregnant or plan to become pregnant. It is not known whether JORNAY PM will harm your unborn baby.
 - There is a pregnancy registry for females who are exposed to JORNAY PM during pregnancy. The purpose of the registry is to collect information about the health of females exposed to JORNAY PM and their baby. If you or your child becomes pregnant during treatment with JORNAY PM, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants. You can register by calling 1-866-961-2388.
- are breastfeeding or plan to breastfeed. JORNAY PM passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with JORNAY PM.

Tell your healthcare provider about all of the medicines that you or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

JORNAY PM and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted during treatment with JORNAY PM.

Your healthcare provider will decide whether JORNAY PM can be taken with other medicines.

Especially tell your healthcare provider if you or your child takes medicine to treat depression, including MAOIs.

Know the medicines that you or your child takes. Keep a list of the medicines with you to show your healthcare provider and pharmacist when you or your child get a new medicine.

Do not start any new medicine during treatment with JORNAY PM without talking to your or your child's healthcare provider first.

How should JORNAY PM be taken?

- Take JORNAY PM exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose and timing of the JORNAY PM dose if needed.
- **Take JORNAY PM by mouth 1 time each day in the evening between 6:30 p.m. and 9:30 p.m.**
- Take JORNAY PM at the same time each evening. JORNAY PM **should not** be taken in the morning.
- JORNAY PM can be taken with or without food, but take it the same way each time.
- JORNAY PM capsules may be swallowed whole, or if JORNAY PM capsules cannot be swallowed whole, the capsules may be opened and sprinkled onto applesauce. Make sure to sprinkle all the JORNAY PM onto the applesauce. The JORNAY PM dose should not be divided.
 - swallow **all** the applesauce and medicine mixture right away
 - **do not** chew the applesauce and medicine mixture
 - **do not** store the applesauce and medicine mixture
- If a dose of JORNAY PM is missed, it should be taken as soon as you remember the same evening. If you do not remember until the next morning you should not take the dose. Wait until that evening to take the next scheduled dose.
A missed dose should not be taken in the morning.

If you or your child take too much JORNAY PM, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should be avoided during treatment with JORNAY PM?

- Avoid drinking alcohol during treatment with JORNAY PM. This may cause a faster release of the JORNAY PM medicine.

What are possible side effects of JORNAY PM?

JORNAY PM may cause serious side effects, including:

- See **"What is the most important information I should know about JORNAY PM?"**
- **Painful and prolonged erections (priapism).** Priapism has happened in males who take products that contain methylphenidate. If you or your child develops priapism, get medical help right away.

- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).**

Signs and symptoms may include:

- fingers or toes may feel numb, cool, or painful
- fingers or toes may change color from pale, to blue, to red

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

Call your healthcare provider right away if you or your child has any signs of unexplained wounds appearing on fingers or toes during treatment with JORNAY PM.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with JORNAY PM. JORNAY PM treatment may be stopped if your child is not gaining weight or height.
- **Eye problems (increased pressure in the eye and glaucoma).** Call your healthcare provider right away if you or your child develop changes in your vision or eye pain, swelling, or redness.
- **New or worsening tics or worsening Tourette's syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with JORNAY PM.

The most common side effects of methylphenidate products in children, adolescents, and adults with ADHD include:

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| • decreased appetite | • stomach pain | • irritability |
| • trouble sleeping | • weight loss | • mood swings (affect lability) |
| • nausea | • anxiety | • increased heart rate |
| • vomiting | • dizziness | • increased blood pressure |
| • indigestion | | |

The most common side effects of JORNAY PM, in children age 6 to 12 with ADHD include:

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| • trouble sleeping | • nausea |
| • decreased appetite | • mood swings |
| • restlessness (psychomotor hyperactivity) | • vomiting |
| • headache | |

These are not all the possible side effects of JORNAY PM.

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 JORNAY PM?

- Store JORNAY PM at room temperature between 68°F to 77°F (20°C to 25°C).
- Store JORNAY PM in a safe place, like a locked cabinet. Protect from humidity.
- Dispose of remaining, unused, or expired JORNAY PM by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix JORNAY PM with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away JORNAY PM in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicine.

Keep JORNAY PM and all medicines out of the reach of children.

General information about the safe and effective use of JORNAY PM.

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

You can ask your doctor or pharmacist for information about JORNAY PM that is written for healthcare professionals.

What are the ingredients in JORNAY PM?

Active Ingredient: methylphenidate hydrochloride

Inactive Ingredients: dibutyl sebacate, diglycerides, ethylcellulose, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer Type B, microcrystalline cellulose, monoglycerides, polysorbate 80, and talc.

The capsule shell of 20 and 40 mg strength capsules contains FD&C Blue #1, hypromellose, titanium dioxide, yellow iron oxide, and black ink for the imprint. The capsule shell of 60 and 80 mg strength capsules contains FD&C Blue #1, hypromellose, titanium dioxide, and black ink for the imprint. The capsule shell of 100 mg strength capsule contains black iron oxide, FD&C Blue #1, hypromellose, red iron oxide, titanium dioxide, black ink, and white ink for the imprint.

Manufactured for Ironshore Pharmaceuticals Inc.:

For more information about JORNAY PM go to www.jornaypm.com or call 1-877-938-4766.