

IMPORTANT SAFETY INFORMATION

BOXED WARNING: ABUSE, MISUSE, AND ADDICTION

JORNAY PM has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including JORNAY PM, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection. Before prescribing JORNAY PM, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout JORNAY PM treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse and addiction.

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of JORNAY PM. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

JORNAY PM can cause serious adverse reactions and patients should be monitored for the following:

- *Risks to Patients with Serious Cardiac Disease: Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.*
- *Increased Blood Pressure and Heart Rate.*
- *Psychiatric Adverse Reactions: Including exacerbation of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder, induction of a manic episode in patients with bipolar disorder, and new psychotic or manic symptoms. Prior to initiating treatment, screen patients for risk factors for psychiatric adverse reactions. If such symptoms occur, consider discontinuing JORNAY PM.*
- *Priapism: Patients should seek immediate medical attention.*
- *Peripheral Vasculopathy, including Raynaud's Phenomenon: Observe patients for digital changes during treatment.*
- *Weight Loss and Long-Term Suppression of Growth in Pediatric Patients: Monitor height and weight. JORNAY PM is not approved for use and is not recommended in pediatric patients below 6 years of age*

- *Increased Intraocular Pressure (IOP) and Glaucoma: Patients at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist. Closely monitor patients with a history of abnormally increased IOP or open angle glaucoma.*
- *Onset or Exacerbation of Motor and Verbal Tics and Worsening of Tourette's Syndrome.*

ADVERSE REACTIONS

- The most common ($\geq 5\%$ and twice the rate of placebo) adverse reactions with methylphenidate are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- Additional adverse reactions ($\geq 5\%$ and twice the rate of placebo) in JORNAY PM-treated pediatric patients 6 to 12 years are headache, psychomotor hyperactivity, and mood swings.

DRUG INTERACTIONS

- Antihypertensive drugs: Monitor blood pressure; adjust dosage of antihypertensive drug as needed.

To report SUSPECTED ADVERSE REACTIONS, contact Collegium Pharmaceutical, Inc. at 1-855-331-5615 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATION

JORNAY PM (methylphenidate HCl extended-release capsules) is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

Limitations of Use:

The use of JORNAY PM is not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g., weight loss) than patients 6 years and older at the same dosage.

Please [click here](#) for Full Prescribing Information, including Boxed Warning