JORNAY PM®

methylphenidate HCl CII

extended-release capsules

20mg 40mg 60mg 80mg 100mg

Dosing Guide

A quick reference for dosing and optimizing JORNAY PM for your patients

20 mg 40 mg 60 mg 80 mg 100 mg

Capsules shown are not actual size.

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.

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.

Please see additional Important Safety Information on the following pages and Full Prescribing Information, including Boxed Warning.

A Different Way to Dose

JORNAY PM is a once-daily capsule that **should be taken in the evening.** In clinical trials, the most common dosing time was 8 PM[1,2]

The **recommended starting dose** for patients 6 years and older **is 20 mg**[1]

Absorbed in the colon, resulting in a gradual onset and offset of effect, unlike medications absorbed in the upper gastrointestinal (GI) tract[3]

Treatment **effects will be felt the following morning** when the patient wakes[1,3]

Reassure patients and caregivers that although the medication is taken at night, it will only start working the following morning

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information on the following pages and Full Prescribing Information, including Boxed Warning.

Tips for Starting and Optimizing Treatment

Adjust dosing time between 6:30 PM and 9:30 PM, as needed, to fine-tune symptom control[1]

When titrating, **first titrate to achieve efficacy**[1]

After efficacy is achieved, **titrate to extend the duration of efficacy**[1]

Start at 20 mg and increase the dose by 20 mg in weekly increments up to a maximum of 100 mg daily[1]

JORNAY PM®
methylphenidate HCl CII
extended-release capsules

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information on the following pages and Full Prescribing Information, including Boxed Warning.

How to Take JORNAY PM

If the patient cannot swallow the capsule whole, it may be opened and the entire contents sprinkled onto applesauce (to be consumed immediately and entirely without chewing)[1]

Be sure to advise patients to take JORNAY PM consistently with or without food[1]

Jornay PM®
methylphenidate HCl CII
extended-release capsules
20mg 40mg 60mg 80mg 100mg

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

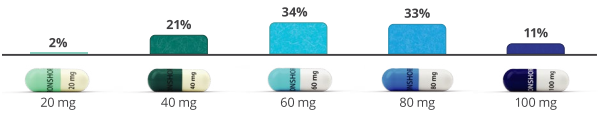
JORNAY PM can cause serious adverse reactions and patients should be monitored for the following:

- *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.

Please see additional Important Safety Information on the following pages and Full Prescribing Information, including Boxed Warning.

Alert patients and caregivers that it may take a few titrations before dosing is fully optimized

Percentage of Patients at Optimized Dose[2]



Capsules shown are not actual size.

In Study 1, 64% of patients were dosed at 8 PM. The mean final dose of JORNAY PM was 66.2 mg.[2,4]

Visit jornaypm-pro.com to see how JORNAY PM with dose-dependent duration may help your patients

Jornay PM®
methylphenidate HCl CII
extended-release capsules

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

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

- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* Observe patients for digital changes during treatment.

Please see additional Important Safety Information on the following pages and Full Prescribing Information, including Boxed Warning.

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.

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.

Please see additional Important Safety Information on the following pages and Full Prescribing Information, including Boxed Warning.

IMPORTANT SAFTEY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

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

- *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.
- *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 (≥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 (≥5% and twice the rate of placebo) in JORNAY PM-treated pediatric patients 6 to 12 years are headache, psychomotor hyperactivity, and mood swings.

Please see additional Important Safety Information on the following page and Full Prescribing Information, including Boxed Warning.

For more information on the unique benefits of JORNAY PM, please visit jornaypm-pro.com

IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

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

To report SUSPECTED ADVERSE REACTIONS, contact Ironshore at **1-877-938-4766**, or FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Please see Full Prescribing Information, including Boxed Warning.

REFERENCES: 1. JORNAY PM® [package insert]. Ironshore Pharmaceuticals & Development, Inc. **2.** Childress AC, Cutler AJ, Marraffino A, et al. A randomized, double-blind, placebo-controlled study of HLD200, a delayed-release and extended-release methylphenidate, in children with attention-deficit/hyperactivity disorder: an evaluation of safety and efficacy throughout the day and across settings. *J Child Adolesc Psychopharmacol.* 2020;30(1):2-14. **3.** Childress A, Mehrotra S, Gobburu J, McLean A, DeSousa NJ, Incledon B. Single-dose pharmacokinetics of HLD200, a delayed-release and extended-release methylphenidate formulation, in healthy adults and in adolescents and children with attention-deficit/hyperactivity disorder. *J Child Adolesc Psychopharmaco*l. 2018;28(1):10-18. **4.** Childress AC, Uchida CL, Po MD, DeSousa NJ, Incledon B. A post-hoc comparison of prior ADHD medication dose and optimized delayed-release and extended-release methylphenidate dose in a pivotal phase III trial. *Clin Ther*. 2020;42(12):2332-2340.

jornay PM®

methylphenidate HCl CII

extended-release capsules

20mg 40mg 60mg 80mg 100mg

IRONSHORE