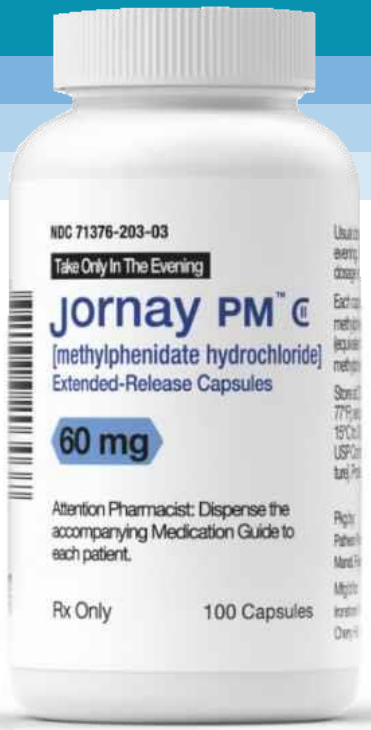
Jornay PM (methylphenidate)



NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Jornay PM
- **Generic name:** Methylphenidate HCl
- **Pharmacological class:** CNS stimulant
- **Strength and Formulation:** 20mg, 40mg, 60mg, 80mg, 100mg; extended-release capsules
- **Manufacturer:** Ironshore Pharmaceuticals
- **How supplied:** Bottles—100
- **Legal Classification:** CII

Indication

- Treatment of **attention deficit hyperactivity disorder**

Dosage & Administration

- <6yrs: not established
- Swallow whole or may open caps and sprinkle contents onto applesauce; do not chew beads
- **Give only in the PM**; avoid AM dose
- **≥6yrs**: initially 20mg once daily at **8PM** (may adjust between 6:30PM–9:30PM)
- May titrate in 20mg increments weekly; dose >100mg/day: not recommended

Dosage & Administration

- Discontinue if no improvement seen after 1 month
- Switching from other methylphenidate products: discontinue and follow Jornay PM titration schedule
- Not interchangeable on a mg-per-mg basis

Considerations for Special Populations

- **Pregnancy:** published studies and postmarketing reports on methylphenidate use during pregnancy are insufficient to inform a drug-associated risk of adverse pregnancy-related outcomes; CNS stimulants can cause vasoconstriction and thereby decrease placental perfusion

- **Nursing mothers:** monitor breastfeeding infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain

Considerations for Special Populations

- **Pediatric:** safety and effectiveness in pediatric patients less than 6 years have not been established; long-term efficacy of methylphenidate in pediatric patients has not been established
  - Growth should be monitored during treatment with stimulants; patients who are not growing or gaining weight as expected may need to have their treatment interrupted
- **Elderly:** not studied in patients older than 65 years of age

Boxed Warning

- High potential for **abuse** and **dependence**
- Assess the risk of abuse prior to prescribing; monitor for signs of abuse and dependence while on therapy

Contraindications

- History of **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
- Receiving **concomitant treatment with monoamine oxidase (MAO) inhibitors**, or within 14 days following discontinuation of a monoamine oxidase inhibitor, because of the risk of hypertensive crisis

Warnings/Precautions

- High potential for **abuse** and **dependence**; monitor
- Increased risk of sudden death, stroke, and MI; assess for presence of **cardiac disease** before initiating
- Avoid in known structural cardiac abnormalities, cardiomyopathy, serious arrhythmias, coronary artery disease, and other cardiac problems
- Pre-existing psychotic disorder
- Bipolar disorder
- Screen for risk factors of developing a manic episode prior to initiation
- Consider discontinuing if new psychotic/manic symptoms occur

Warnings/Precautions

- Peripheral vasculopathy, including Raynaud's phenomenon; monitor for digital changes
- Monitor growth (esp. children), BP, HR
- Reduce dose or discontinue if paradoxical aggravation of symptoms occur
- Reevaluate periodically

Interactions

- Do not administer Jornay PM concomitantly with **MAOIs** or within 14 days after discontinuing MAOI treatment
- Concomitant use of MAO inhibitors and CNS stimulants can cause **hypertensive crisis**

Adverse Reactions

- **Most common** (≥5%): decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure
- **Others**: priapism, hypersensitivity, cardiovascular reactions
- **Children also**: headache, psychomotor hyperactivity, mood swings

Mechanism of Action

- Methylphenidate hydrochloride is a central nervous system stimulant
- The exact mode of therapeutic action in ADHD is not known
- Methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space

Clinical Studies

- The efficacy of Jornay PM was established in 2 clinical studies in pediatric patients 6 to 12 years of age (N=278) who met DSM-5 criteria for ADHD inattentive, hyperactive-impulsive, or combined inattentive/hyperactive-impulsive subtypes

Clinical Studies

- **Study 1:**
  - 6-week, open-label, dose-optimization phase in which patients (n=117) received Jornay PM, followed by 1-week, double-blind, placebo-controlled withdrawal phase in which patients were randomized to continue Jornay PM (n=64; mean dose 67mg) or switch to placebo (n=53)
  - After 1 week of double-blind treatment, patients were evaluated in an analog classroom over a12-hour period using the Swanson, Kotkin, Agler, M-Flynn, and Pelham Scale (SKAMP), a 13-item teacher rated scale that assesses manifestations of ADHD in a classroom setting; possible scores range from 0 (normal/no impairment) to 78 (maximal impairment)

Clinical Studies

- **Results**:
  - The primary efficacy endpoint, the model-adjusted average of all post-dose SKAMP combined scores measured during the 12-hour analog testing period, was statistically significantly better (lower) for Jornay PM compared with placebo
  - Jornay PM showed improvement over placebo at time points (9 and 10AM, and 12, 2, 4, 6 and 7PM) on the next day after the evening dosing

Clinical Studies

- **Study 2**:
  - 3-week, multicenter, randomized, double-blind, placebo-controlled, parallel group study
  - Patients randomized to PM dose of 40, 60, or 80mg Jornay PM (n=81) or placebo (n=80)
  - Primary efficacy measure was ADHD Rating Scale (ADHD-RS-IV) Total Score, measuring severity of manifestations throughout the day; possible scores range from 0 (no ADHD manifestations) to 54 (severe symptoms of both ADHD subtypes)

Clinical Studies

- **Results**:
  - After 3 weeks of treatment, ADHD-RS-IV total scores were statistically significantly better (lower) for Jornay PM than placebo
  - Jornay PM group: from mean baseline score of 43.1 to 24.1
  - Placebo group: from mean baseline score of 43.5 to 31.2

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/jornay-pm/