HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use JORNAY PM® safely and effectively. See full prescribing information for JORNAY PM.

JORNAY PM (methylphenidate hydrochloride) extended-release capsules, for oral use, CII
Initial U.S. Approval: 1955

WARNING: ABUSE, MISUSE AND ADDICTION

See full prescribing information for complete boxed warning.

- **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 (5.1, 9.2, 10):**
- **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 treatment, reassess each patient's risk and frequently monitor for signs and symptoms of abuse, misuse, and addiction.**

RECENT MAJOR CHANGES

Indications and Usage (1)	09/2025
Warnings and Precautions (5.7)	09/2025

INDICATIONS AND USAGE

JORNAY PM is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. (1)

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 (5.7, 8.4).

DOSAGE AND ADMINISTRATION

- JORNAY PM should be taken only in the evening. (2.2)
- Recommended starting dose for patients 6 years and above is 20 mg daily in the evening. (2.2)
- Adjust the timing of administration between 6:30 p.m. and 9:30 p.m. to optimize the tolerability and the efficacy the next morning and throughout the day.
- Dosage may be increased weekly in increments of 20 mg per day up to a maximum daily dose of 100 mg. (2.2)
- Patients are advised to take JORNAY PM consistently either with food or without food. (2.2)
- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce. (2.2)
- To avoid substitution errors and overdosage, do not substitute for other methylphenidate products on a milligram-per-milligram basis. (2.4)

DOSAGE FORMS AND STRENGTHS

- Extended-release capsules: 20 mg, 40 mg, 60 mg, 80 mg, and 100 mg. JORNAY PM exhibits both delayed-release and extended-release properties. (3)

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or product components. (4)
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days. (4)

WARNINGS AND PRECAUTIONS

- *Risks to Patients with Serious Cardiac Disease:* Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac disease. (5.2)
- *Increased Blood Pressure and Heart Rate:* Monitor blood pressure and pulse. (5.3)
- *Psychiatric Adverse Reactions:* Prior to initiating JORNAY PM, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing JORNAY PM. (5.4)
- *Priapism:* If abnormally sustained or frequent and painful erections occur, patients should seek immediate medical attention. (5.5)
- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* Careful observation for digital changes is necessary during JORNAY PM treatment. Further clinical evaluation (e.g. rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy (5.6)
- *Long-Term Suppression of Growth in Pediatric Patients:* Closely monitor growth (height and weight) in pediatric patients. Pediatric patients not growing or gaining height or weight as expected may need to have their treatment interrupted. (5.7)
- *Acute Angle Closure Glaucoma:* JORNAY PM-treated patients considered at risk for acute angle closure glaucoma (e.g. patients with significant hyperopia) should be evaluated by an ophthalmologist (5.8)
- *Increased Intraocular Pressure (IOP) and Glaucoma:* Prescribe JORNAY PM to patients with open-angle glaucoma or abnormally increased IOP only if the benefit of treatment is considered to outweigh the risk. Closely monitor patients with a history of increased IOP or open angle glaucoma. (5.9)
- *Motor and Verbal Tics, and Worsening of Tourette's Syndrome:* Before initiating JORNAY PM, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome. Discontinue treatment if clinically appropriate. (5.10)

ADVERSE REACTIONS

Based on accumulated data from other methylphenidate products, the most common (≥5% and twice the rate of placebo) adverse reactions for adult and pediatric patients are: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.

Additional adverse reactions (≥5% and twice the rate of placebo) in JORNAY PM-treated pediatric patients 6 to 12 years: headache, psychomotor hyperactivity, and mood swings. (6.1)

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

DRUG INTERACTIONS

Antihypertensive Drugs: Monitor blood pressure. Adjust dosage of antihypertensive drug as needed (7.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 09/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

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 *[see Overdosage (10)]*, 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 *[see Warnings and Precautions (5.1) and Drug Abuse and Dependence (9.2)]*.

1 INDICATIONS AND USAGE

JORNAY PM is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older *[see Clinical Studies (14)]*.

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 *[see Warnings and Precautions (5.7), Use in Specific Populations (8.4)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Pretreatment Screening

Prior to treating patients with JORNAY PM, assess:

- for the presence of cardiac disease (i.e., perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam) *[see Warnings and Precautions (5.2)]*.
- the family history and clinically evaluate patients for motor or verbal tics or Tourette's syndrome *[see Warnings and Precautions (5.10)]*.

2.2 Recommended Dosage

The recommended starting dosage of JORNAY PM in patients 6 years and older is 20 mg once daily orally in the evening. Do not take JORNAY PM in the morning. The dose may be titrated weekly in increments of 20 mg. A daily dosage above 100 mg has not been studied and is not recommended.

Initiate dosing at 8:00 p.m. Adjust the timing of administration between 6:30 p.m. and 9:30 p.m. to optimize the tolerability and efficacy the next morning and throughout the day. In clinical trials of patients aged 6 to 12 years, the most common dosing time (>70% of patients) was 8:00 p.m., with an allowed range between 6:30 p.m. and 9:30 p.m. Following determination of the optimal administration time, advise patients to maintain a consistent dosing time.

Advise patients to take JORNAY PM consistently, either with food or without food.

Patients who miss their dose of JORNAY PM at the regularly scheduled time should take it as soon as they remember that same evening. If a patient remembers the missed dose the following morning, they should skip the missed dose and wait until their next scheduled evening administration.

2.3 Administration Instructions

JORNAY PM may be taken whole, or the capsule may be opened, and the entire contents sprinkled onto applesauce. If the patient is using the sprinkled administration method, the sprinkled applesauce should be consumed immediately; it should not be stored. Patients should take the applesauce with sprinkled beads in its entirety without chewing. The dose of a single capsule should not be divided. The contents of the entire capsule should be taken at the same time.

2.4 Switching from Other Methylphenidate Products

If switching from other methylphenidate products, discontinue that treatment, and titrate with JORNAY PM using the titration schedule described above.

Do not substitute JORNAY PM for other methylphenidate products on a milligram-per-milligram basis because these products have different pharmacokinetic profiles from JORNAY PM and may have different methylphenidate base composition *[see Description (11) and Clinical Pharmacology (12.3)]*.

2.5 Dosage Reduction and Discontinuation

If paradoxical aggravation of symptoms or other adverse reactions occur, reduce dosage or, if necessary, discontinue JORNAY PM. If improvement is not observed after appropriate dosage adjustment over a one-month period, discontinue JORNAY PM.

3 DOSAGE FORMS AND STRENGTHS

JORNAY PM (methylphenidate hydrochloride) extended-release capsules exhibit both delayed-release and extended-release properties and are available in the following dose strengths:

- 20 mg capsules with ivory opaque body and light green opaque cap;
- 40 mg capsules with ivory opaque body and blue-green opaque cap;
- 60 mg capsules with white opaque body and powder blue opaque cap;
- 80 mg capsules with white opaque body and light blue opaque cap; and
- 100 mg capsules with white opaque body and dark blue opaque cap.

All capsules are imprinted with the dose in black on the body and “IRONSHORE” in black on the cap, except for the 100 mg capsule, on which “IRONSHORE” is imprinted in white.

4 CONTRAINDICATIONS

JORNAY PM is contraindicated in patients:

- With a 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 *[see Adverse Reactions (6)]*.

- 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 *[see Drug Interactions (7.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Abuse, Misuse, and Addiction

JORNAY PM has a high potential for abuse and misuse. The use of JORNAY PM exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. JORNAY PM can be diverted for non-medical use into illicit channels or distribution *[see Drug Abuse and*

Dependence (9.2]. Misuse and abuse of CNS stimulants, including JORNAY PM, can result in overdose and death *[see Overdosage (10)]*, 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 and proper disposal of any unused drug. Advise patients to store JORNAY PM in a safe place, preferably locked, and instruct patients to not give JORNAY PM to anyone else. 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.

5.2 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 JORNAY PM use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

5.3 Increased Blood Pressure and Heart Rate

CNS stimulants may cause an increase in blood pressure (mean increase approximately 2 to 4 mmHg) and heart rate (mean increase approximately 3 to 6 bpm). Some patients may have larger increases.

Monitor all JORNAY PM-treated patients for hypertension and tachycardia.

5.4 Psychiatric Adverse Reactions

Exacerbation of Pre-existing Psychosis

CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating JORNAY PM treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression).

New Psychotic or Manic Symptoms

CNS stimulants, at the recommended dosage, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. In a pooled analysis of multiple short-term placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients, compared with 0% of placebo-treated patients. If such symptoms occur, consider discontinuing JORNAY PM.

5.5 Priapism

Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate use in both adult and pediatric male patients. Although priapism was not reported with methylphenidate initiation, it developed after some time on methylphenidate, often subsequent to an increase in dosage. Priapism also occurred during methylphenidate withdrawal (drug holidays or during discontinuation).

JORNAY PM-treated patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.

5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon

CNS stimulants, including JORNAY PM, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, sequelae

have included digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports and at the therapeutic dosage of CNS stimulants in all age groups throughout the course of treatment. Signs and symptoms generally improved after dosage reduction or discontinuation of the CNS stimulant.

Careful observation for digital changes is necessary during JORNAY PM treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for JORNAY PM-treated patients who develop signs or symptoms of peripheral vasculopathy.

5.7 Long-term Suppression of Growth in Pediatric Patients

JORNAY PM is not approved for use and is not recommended in pediatric patients below 6 years of age *[see Use in Specific Populations (8.4)]*.

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients.

Careful follow-up of weight and height in pediatric patients ages 7 to 10 years who were randomized to either methylphenidate or nonmedication-treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and nonmedication-treated pediatric patients over 36 months (to the ages of 10 to 13 years), suggests that pediatric patients who received methylphenidate for 7 days per week throughout the year had a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this development period.

Closely monitor growth (weight and height) in JORNAY PM-treated pediatric patients. Pediatric patients not growing or gaining height or weight as expected may need to have their treatment interrupted.

5.8 Acute Angle Closure Glaucoma

There have been reports of angle closure glaucoma associated with methylphenidate treatment.

Although the mechanism is not clear, JORNAY PM-treated patients considered at risk for acute angle closure glaucoma (e.g., patients with significant hyperopia) should be evaluated by an ophthalmologist.

5.9 Increased Intraocular Pressure and Glaucoma

There have been reports of an elevation of intraocular pressure (IOP) associated with methylphenidate treatment *[see Adverse Reactions (6.2)]*.

Prescribe JORNAY PM to patients with open-angle glaucoma or abnormally increased IOP only if the benefit of treatment is considered to outweigh the risk. Closely monitor JORNAY PM-treated patients with a history of abnormally increased IOP or open angle glaucoma.

5.10 Motor and Verbal Tics, and Worsening of Tourette's Syndrome

CNS stimulants, including methylphenidate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported *[see Adverse Reactions (6.2)]*.

Before initiating JORNAY PM, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor JORNAY PM-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in more detail in other sections of the labeling:

- Abuse, Misuse, and Addiction *[see Boxed Warning, Warnings and Precautions (5.1), and Drug Abuse and Dependence (9.2, 9.3)]*
- Hypersensitivity to methylphenidate or other components of JORNAY PM *[see Contraindications (4)]*

- Hypertensive crisis when used concomitantly with monoamine oxidase inhibitors *[see Contraindications (4) and Drug Interactions (7.1)]*
- Risks to Patients with Serious Cardiac Disease *[see Warnings and Precautions (5.2)]*
- Increased Blood Pressure and Heart Rate *[see Warnings and Precautions (5.3)]*
- Psychiatric Adverse Reactions *[see Warnings and Precautions (5.4)]*
- Priapism *[see Warnings and Precautions (5.5)]*
- Peripheral Vasculopathy, including Raynaud's Phenomenon *[see Warnings and Precautions (5.6)]*
- Long-term Suppression of Growth in Pediatric Patients *[see Warnings and Precautions (5.7)]*
- Acute Angle Closure Glaucoma *[see Warnings and Precautions (5.8)]*
- Increased Intraocular Pressure and Glaucoma *[see Warnings and Precautions (5.9)]*
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome *[see Warnings and Precautions (5.10)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Adverse Reactions in Studies with Other Methylphenidate Products in Children, Adolescents, and Adults with ADHD

Commonly reported (≥2% of the methylphenidate group and at least twice the rate of the placebo group) adverse reactions from placebo-controlled trials of methylphenidate products include: appetite decreased, weight decreased, nausea, abdominal pain, dyspepsia, dry mouth, vomiting, insomnia, anxiety, nervousness, restlessness, affect lability, agitation, irritability, dizziness, vertigo, tremor, blurred vision, blood pressure increased, heart rate increased, tachycardia, palpitations, hyperhidrosis, and pyrexia.

Adverse Reactions in Studies with JORNAY PM in Pediatric Patients (6 to 12 years) with ADHD

The safety of JORNAY PM was evaluated in 280 patients (6 to 12 years of age) who participated in two controlled clinical studies of patients with ADHD *[see Clinical Studies (14)]*.

Study 1, conducted in pediatric patients 6 to 12 years of age, was comprised of a 6-week open-label dose-optimization phase in which all patients received JORNAY PM (n=125; mean dose 50 mg), followed by a 1-week, double-blind controlled phase in which patients were randomized to continue JORNAY PM (n=65) or switch to placebo (n=54). During the open-label JORNAY PM treatment phase, adverse reactions reported in > 5% of patients included: any insomnia (41%), decreased appetite (27%), affect lability (22%), headache (19%), upper respiratory tract infection (17%), upper abdominal pain (9%), nausea or vomiting (9%), increased diastolic blood pressure (8%), tachycardia (7%), and irritability (6%). Three patients discontinued treatment because of adverse reactions of affect lability, panic attacks, and agitation and aggression. Because of the trial design (6-week open-label active treatment phase followed by a 1-week, randomized, double-blind, placebo-controlled withdrawal), the adverse reaction rates described in the double-blind phase are lower than expected in clinical practice. No difference occurred in the incidence of adverse reactions between JORNAY PM and placebo during the 1-week, double-blind, placebo-controlled treatment phase.

Study 2 was a 3-week, placebo-controlled study of JORNAY PM (n=81; mean dose 52mg) in pediatric patients 6 to 12 years.

Most Common Adverse Reactions (incidence of ≥ 5% and at a rate at least twice placebo): any insomnia, decreased appetite, headache, vomiting, nausea, psychomotor hyperactivity, and affect lability or mood swings.

One patient in the JORNAY PM group discontinued from the study due to mood swings.

Table 1 provides the incidence of adverse reactions reported in Study 2 (incidence of 2% or more and at least twice placebo) among pediatric patients 6 to 12 years in a 3-week clinical trial.

Table 1: Adverse Reactions that Occurred in ≥2% of JORNAY PM-treated Pediatric Patients and Greater than Placebo in a 3-Week ADHD Study (Study 2)

Body Organ System	Adverse Reaction	JORNAY PM (N=81)	Placebo (N=80)
Psychiatric disorders	Any insomnia	33%	9%
	Initial insomnia	14%	5%
	Middle insomnia	11%	4%
	Terminal insomnia	11%	1%
	Insomnia, not specified	4%	1%
	Affect lability/ Mood swings	6%	1%
Metabolism and nutrition disorders	Decreased appetite	19%	4%
Nervous system disorders	Headache	10%	5%
	Psychomotor hyperactivity	5%	1%
Cardiovascular	Blood pressure diastolic increased	7%	4%
Gastrointestinal disorders	Vomiting	9%	0%
	Nausea	6%	0%
Infections and infestations	Nasopharyngitis	3%	1%
	Pharyngitis streptococcal	3%	0%
Injury, poisoning and procedural complications	Contusion	3%	0%
Musculoskeletal and connective tissue disorders	Back pain	3%	0%
Skin and subcutaneous tissue disorders	Rash	2%	0%

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of methylphenidate products. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions are as follows:

Blood and Lymphatic System Disorders: Pancytopenia, Thrombocytopenia, Thrombocytopenic purpura

Cardiac Disorders: Angina pectoris, Bradycardia, Extrasystole, Supraventricular tachycardia, Ventricular extrasystole

Eye Disorders: Diplopia, Increased intraocular pressure, Mydriasis, Visual impairment

General Disorders: Chest pain, Chest discomfort, Hyperpyrexia

Immune System Disorders: Hypersensitivity reactions such as Angioedema, Anaphylactic reactions, Auricular swelling, Bullous conditions, Exfoliative conditions, Urticarias, Pruritus, Rashes, Eruptions, and Exanthemas

Investigations: Alkaline phosphatase increased, Bilirubin increased, Hepatic enzyme increased, Platelet count decreased, White blood cell count abnormal, Severe hepatic injury

Musculoskeletal, Connective Tissue and Bone Disorders: Arthralgia, Myalgia, Muscle twitching, Rhabdomyolysis

Nervous System Disorders: Convulsion, Grand mal convulsion, Dyskinesia, Serotonin syndrome in combination with serotonergic drugs, Motor and Verbal Tics

Psychiatric Disorders: Disorientation, Hallucination, Hallucination auditory, Hallucination visual, Libido changes, Mania

Urogenital System: Priapism

Skin and Subcutaneous Tissue Disorders: Alopecia, Erythema

Vascular Disorders: Raynaud's phenomenon

7 DRUG INTERACTIONS

7.1 MAO Inhibitors

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. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure *[see Contraindications (4)]*.

7.2 Antihypertensive Drugs

JORNAY PM may decrease the effectiveness of drugs used to treat hypertension. Monitor blood pressure and adjust the dosage of the antihypertensive drug as needed [see Warnings and Precautions (5.3)].

7.3 Halogenated Anesthetics

Concomitant use of halogenated anesthetics and JORNAY PM may increase the risk of sudden blood pressure and heart rate increase during surgery. Monitor blood pressure and avoid use of JORNAY PM in patients being treated with anesthetics on the day of surgery.

7.4 Risperidone

The combined use of methylphenidate with risperidone when there is a change in dose of either or both medications may increase the risk of extrapyramidal symptoms (EPS). Monitor for signs of EPS.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to JORNAY PM during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.

Risk Summary

Published studies and postmarketing reports on methylphenidate use during pregnancy are insufficient to inform a drug-associated risk of adverse pregnancy-related outcomes *[see Data]*. No teratogenic effects were observed in embryo-fetal development studies with oral administration of methylphenidate to pregnant rats and rabbits during organogenesis at doses up to 2 and 9 times the maximum recommended human dose (MRHD) of 100

mg/day given to adolescents on a mg/m^2 basis, respectively. However, spina bifida was observed in rabbits at a dose 31 times the MRHD given to adolescents. A decrease in pup body weight was observed in a pre-and post-natal development study with oral administration of methylphenidate to rats throughout pregnancy and lactation at doses 3.5 times the MRHD given to adolescents *[see Data]*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2% to 4% and of miscarriage is 15% to 20% of clinically recognized pregnancies.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

CNS stimulant medications, such as JORNAY PM, can cause vasoconstriction and thereby decrease placental perfusion. No fetal and/or neonatal adverse reactions have been reported with the use of therapeutic doses of methylphenidate during pregnancy; however, premature delivery and low birth weight infants have been reported in amphetamine-dependent mothers.

Data

Human Data

A limited number of pregnancies have been reported in published observational studies and postmarketing reports describing methylphenidate use during pregnancy. Due to the small number of methylphenidate-exposed pregnancies with known outcomes, these data cannot definitely establish or exclude any drug-associated risk during pregnancy. Methodological limitations of these observational studies include small sample size, concomitant use of other medications, lack of detail regarding dose and duration of exposure to methylphenidate and nongeneralizability of the enrolled populations.

Animal Data

In studies conducted in rats and rabbits, methylphenidate was administered orally at doses of up to 75 and 200 mg/kg/day, respectively, during the period of organogenesis. Teratogenic effects (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 31 times the maximum recommended human dose (MRHD) of 100 mg/day given to adolescents on a mg/m^2 basis. The no effect level for embryo-fetal development in rabbits was 60 mg/kg/day (9 times the MRHD given to adolescents on a mg/m^2 basis). There was no evidence of specific teratogenic activity in rats, although increased incidences of fetal skeletal variations were seen at the highest dose level (6 times the MRHD given to adolescents on a mg/m^2 basis), which was also maternally toxic. The no effect level for embryo-fetal development in rats was 25 mg/kg/day (2 times the MRHD given to adolescents on a mg/m^2 basis).

8.2 Lactation

Risk Summary

Limited published literature, based on breast milk sampling from five mothers, reports that methylphenidate is present in human milk, which resulted in infant doses of 0.16% to 0.7% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.1 and 2.7. There are no reports of adverse effects on the breastfed infant and no effects on milk production. However, long-term neurodevelopmental effects on infants from CNS stimulant exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for JORNAY PM and any potential adverse effects on the breastfed infant from JORNAY PM or from the underlying maternal condition.

Clinical Considerations

Monitor breastfeeding infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.

8.4 Pediatric Use

The safety and effectiveness of JORNAY PM have not been established in pediatric patients below the age of 6 years.

In studies evaluating extended-release methylphenidate products, patients 4 to <6 years of age had higher systemic methylphenidate exposures than those observed in older pediatric patients at the same dosage. Pediatric patients 4 to <6 years of age also had a higher incidence of adverse reactions, including weight loss.

The safety and effectiveness of JORNAY PM have been established in pediatric patients ages 6 to 17 years in two adequate and well-controlled clinical studies in pediatric patients 6 to 12 years, pharmacokinetic data in adults, and safety information from other methylphenidate-containing products *[see Clinical Studies (14) and see Clinical Pharmacology (12.3)*].

Long-Term Suppression of Growth

Growth should be monitored during treatment with stimulants, including JORNAY PM. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted *[see Warnings and Precautions (5.7)]*.

Juvenile Animal Toxicity Data

Rats treated with methylphenidate early in the postnatal period through sexual maturation demonstrated a decrease in spontaneous locomotor activity in adulthood. A deficit in acquisition of a specific learning task was observed in females only. The doses at which these findings were observed are at least 2.5 times the maximum recommended human dose (MRHD) of 100 mg/day given to children on a mg/m^2 basis.

In a study conducted in young rats, methylphenidate was administered orally at doses of up to 100 mg/kg/day for 9 weeks, starting early in the postnatal period (postnatal Day 7) and continuing through sexual maturity (postnatal week 10). When these animals were tested as adults (postnatal weeks 13-14), decreased spontaneous locomotor activity was observed in males and females previously treated with ≥ 50 mg/kg/day (approximately ≥ 2.5 times the MRHD of 100 mg/day given to children on a mg/m^2 basis), and a deficit in the acquisition of a specific learning task was seen in females exposed to the highest dose (5 times the MRHD of 100 mg/day given to children on a mg/m^2 basis). The no effect level for juvenile neurobehavioral development in rats was 5 mg/kg/day (0.25 times the MRHD of 100 mg/day given to children on a mg/m^2 basis). The clinical significance of the long-term behavioral effects observed in rats is unknown.

8.5 Geriatric Use

JORNAY PM has not been studied in patients older than 65 years of age.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

JORNAY PM contains methylphenidate, a Schedule II controlled substance.

9.2 Abuse

JORNAY PM has a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction *[see Warnings and Precautions (5.1)]*. JORNAY PM can be diverted for non-medical use into illicit channels or distribution.

Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug addiction is a cluster of

behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence.

Misuse and abuse of methylphenidate may cause increased heart rate, respiratory rate, or blood pressure; sweating; dilated pupils; hyperactivity; restlessness; insomnia; decreased appetite; loss of coordination; tremors; flushed skin; vomiting; and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also been observed with CNS stimulants abuse and/or misuse. Misuse and abuse of CNS stimulants, including JORNAY PM, can result in overdose and death *[see Overdosage (10)]*, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

9.3 Dependence

Physical Dependence

JORNAY PM may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

Withdrawal signs and symptoms after abrupt discontinuation or dose reduction following prolonged use of CNS stimulants including JORNAY PM include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

JORNAY PM may produce tolerance. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

10 OVERDOSAGE

Clinical Effects of Overdose

Overdose of CNS Stimulants is characterized by the following sympathomimetic effects:

- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.
- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.
- Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.

Overdose Management

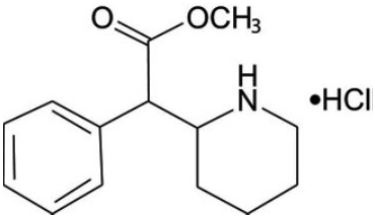
Consider the possibility of multiple drug ingestion. The pharmacokinetic profile of JORNAY PM should be considered when treating patients with overdose. Because methylphenidate has a large volume of distribution and is rapidly metabolized, dialysis is not useful. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

11 DESCRIPTION

JORNAY PM contains methylphenidate hydrochloride, a central nervous system (CNS) stimulant.

Methylphenidate hydrochloride is a white, odorless crystalline powder. Its aqueous solutions are acidic. It is freely soluble in water and in methanol, soluble in alcohol, and slightly soluble in chloroform and in acetone. The chemical name of methylphenidate hydrochloride is *d,l* (racemic) methyl α-phenyl-2-piperidineacetate

hydrochloride. Its molecular formula is $C_{14}H_{19}NO_2$•HCl and the molecular weight is 269.77. Its structural formula is



The molecular formula of the free base is $C_{14}H_{19}NO_2$ and its molecular weight is 233.31.

JORNAY PM extended-release capsules contain beads with two functional film coatings (outer delayed-release and inner extended-release) surrounding a drug core coated with methylphenidate hydrochloride. The outer, delayed-release coating delays the initial release of methylphenidate while the inner extended-release coating controls the release throughout the day. JORNAY PM is available as extended-release capsules for oral use in five strengths. Each capsule contains 20 mg, 40 mg, 60 mg, 80 mg, or 100 mg of methylphenidate hydrochloride, which is equivalent to 17.4 mg, 34.8 mg, 52.2 mg, 69.6 mg, or 87.0 mg of methylphenidate free base, respectively.

JORNAY PM capsules also contain the following 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 is made of 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 is made of FD&C Blue #1, hypromellose, titanium dioxide, and black ink for the imprint. The capsule shell of 100 mg strength capsule is made of black iron oxide, FD&C Blue #1, hypromellose, red iron oxide, titanium dioxide, and black ink, and white ink for the imprint.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Methylphenidate hydrochloride is a central nervous system (CNS) stimulant. The exact mode of therapeutic action in ADHD is not known.

12.2 Pharmacodynamics

Methylphenidate is a racemic mixture comprising the *d*- and *l*-isomers. The *d*-isomer is more pharmacologically active than the *l*-isomer. 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.

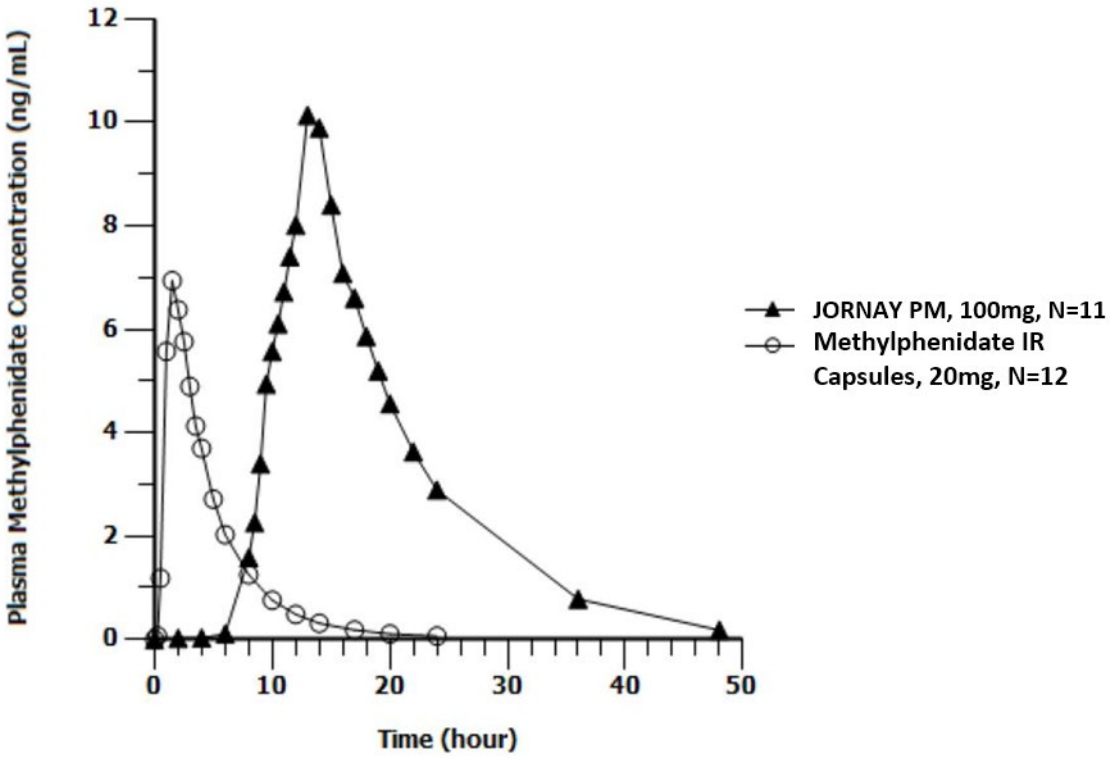
12.3 Pharmacokinetics

The pharmacokinetics of methylphenidate was dose-proportional between 20 mg and 100 mg dose level.

Absorption

The pharmacokinetics of methylphenidate after a single, 100 mg oral dose of JORNAY PM administered in the evening at 9 pm were studied in healthy adults. The initial absorption of methylphenidate into plasma is delayed such that no more than 5% of total drug is available within the first 10 hours after dosing. After the lag period, the absorption of methylphenidate occurs in a single peak with a median T_{max} 14.0 hours, followed by a gradual decline throughout the rest of the day.

Figure 1: Arithmetic Mean Plasma Methylphenidate Concentrations following a Single, Oral, 100 mg Dose of JORNAY PM (Methylphenidate Hydrochloride Extended-Release Capsule) or Methylphenidate Immediate-Release Oral Product Administered in a Crossover Manner to Healthy Adult Subjects



The relative bioavailability of JORNAY PM (given once a day) compared to the same daily dose of a methylphenidate immediate-release oral product (given 3 times a day) in adults is 73.9%.

Food Effects

Compared to the fasted state, JORNAY PM taken with a high-fat meal at night exhibited similar mean $AUC_{0-\infty}$, a 14% lower mean C_{max}, and a median T_{max} extended by approximately 2.5 hours. After JORNAY PM was taken at night, a morning meal had no effect on the pharmacokinetics of methylphenidate.

The pharmacokinetic parameters were similar when JORNAY PM was taken as a whole capsule or when sprinkled on applesauce.

Elimination

The apparent half-life of methylphenidate in adults following oral administration of JORNAY PM was approximately 5.9 hours.

Metabolism

In humans, methylphenidate is metabolized primarily by de-esterification to α-phenyl-piperidine acetic acid (PPAA). The metabolite has little pharmacologic activity.

Excretion

After oral dosing of radiolabeled methylphenidate in humans, about 90% of the radioactivity was recovered in urine. The main urinary metabolite was PPAA, accounting for approximately 80% of the dose.

Alcohol Effect:

In vitro testing showed that approximately 97% of methylphenidate was released from JORNAY PM capsules in 2 hours in the presence of 40% alcohol. The increase in methylphenidate release rate was not observed in the presence of 5 to 20% alcohol. No *in vivo* studies have been conducted to assess the effect of alcohol on drug exposure.

Specific populations:

Pediatric Patients

The pharmacokinetics of methylphenidate after a single, 54 mg oral dose of JORNAY PM administered in the evening at 9 pm were studied in two separate studies in adults and in children and adolescent patients with ADHD between 8 and 17 years of age. The plasma methylphenidate concentration curves were qualitatively similar in healthy adult volunteers, children 8 to 12 years, and adolescents with ADHD. Body weight dose normalized AUC and C_{max} were similar in children, adolescents, and adults. However, there were differences in mean PK parameters between children, adolescents, and adults; children were exposed to higher levels of methylphenidate when provided the same dose of JORNAY PM (C_{max}: children = 11.6 ng/mL, adolescents = 7.2 ng/mL, adults = 6.0 ng/mL; AUC_t: children = 206 ng·hr/mL, adolescents = 106 ng·hr/mL, adults = 83.4 ng·hr/mL).

Patients with Renal Impairment:

There is no experience with the use of JORNAY PM in patients with renal insufficiency. After oral administration of radiolabeled methylphenidate in humans, methylphenidate was extensively metabolized and approximately 80% of the radioactivity was excreted in the urine in the form of PPAA. Since renal clearance is not an important route of methylphenidate clearance, renal insufficiency is expected to have little effect on the pharmacokinetics of JORNAY PM.

Patients with Hepatic Impairment

There is no experience with the use of JORNAY PM in patients with hepatic insufficiency.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis:

In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas, at a daily dose of approximately 60 mg/kg/day. This dose is approximately 1.5 times the maximum recommended human dose (MRHD) of 100 mg/day given to children on a mg/m^2 basis. Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown.

Methylphenidate did not cause any increases in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 2 times the MRHD (children) on a mg/m^2 basis.

In a 24-week carcinogenicity study in the transgenic mouse strain $p53^{+/-}$, which is sensitive to genotoxic carcinogens, there was no evidence of carcinogenicity. Male and female mice were fed diets containing the same concentration of methylphenidate as in the lifetime carcinogenicity study; the high-dose groups were exposed to 60 to 74 mg/kg/day of methylphenidate.

Mutagenesis:

Methylphenidate was not mutagenic in the *in vitro* Ames reverse mutation assay or in the *in vitro* mouse lymphoma cell forward mutation assay. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in an *in vitro* assay in cultured Chinese Hamster Ovary (CHO) cells. Methylphenidate was negative *in vivo* in males and females in the mouse bone marrow micronucleus assay.

Impairment of Fertility:

Methylphenidate did not impair fertility in male or female mice that were fed diets containing the drug in an 18-week continuous breeding study. The study was conducted at doses up to 160 mg/kg/day, approximately 6-times the maximum recommended human dose of 100 mg/day given to adolescents on a mg/m^2 basis.

14 CLINICAL STUDIES

The efficacy of JORNAY PM for the treatment of ADHD was established in two clinical studies of JORNAY PM 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.

Study 1 (NCT#02493777), conducted in pediatric patients 6 to 12 years of age, was comprised of a 6-week, open-label, dose-optimization phase in which all patients (n = 117) received JORNAY PM (once each evening; flexible dosing from 20 mg to 100 mg), followed by a 1-week, double-blind, placebo-controlled withdrawal phase in which patients were randomized to continue JORNAY PM (n=64; mean dose 67 mg once daily) or switch to placebo (n=53). After 1 week of double-blind treatment, patients were evaluated in an analog classroom over a 12-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). The primary efficacy endpoint was the model-adjusted average of all post-dose SKAMP combined scores measured during the 12-hour analog testing period from 8:00 a.m. to 8:00 p.m. The secondary efficacy measure was the morning subscale of the Parent Rating of Evening and Morning Behavior-Revised (PREMB-R AM), to measure manifestations of ADHD in the early morning. This clinician-rated scale is based on parent interview using three questions and assesses manifestations of ADHD during the early morning period. Possible scores range from 0 (no ADHD manifestations) to 9 (severe ADHD manifestations).

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 (Table 2). JORNAY PM showed improvement over placebo at time points (9 and 10 a.m., and 12, 2, 4, 6 and 7 p.m.) on the next day after the evening dosing. Figure 2 shows the LS mean and standard error of SKAMP combined scores at each of the individual time points from 8:00 a.m. to 8:00 p.m. The secondary efficacy endpoint, the PREMB-R AM, was also statistically significantly better (lower) for JORNAY PM versus placebo.

Study 2 (NCT#02520388) was a 3-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study in pediatric patients, 6 to 12 years of age. Patients were randomized to an oral dosage of 40, 60, or 80 mg of JORNAY PM (n=81) or placebo (n=80) once in the evening. The primary efficacy measure was the 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). Normative scores range 18 to 29 in ADHD. The secondary efficacy measure was the Before School Functioning Questionnaire (BSFQ), a clinician-rated 20-item questionnaire assessing ADHD manifestations on a severity scale of 0 to 3. BSFQ is intended to assess early morning before school activities from the time the child awakens and some behaviors not specific to early morning. Possible scores range from 0 (no difficulty) to 60 (severe difficulty).

After 3 weeks of treatment, the ADHD-RS-IV total scores were statistically significantly better (lower) for JORNAY PM than placebo (Table 2). The secondary efficacy endpoint, the BSFQ, was also statistically significantly better (lower) for JORNAY PM versus placebo.

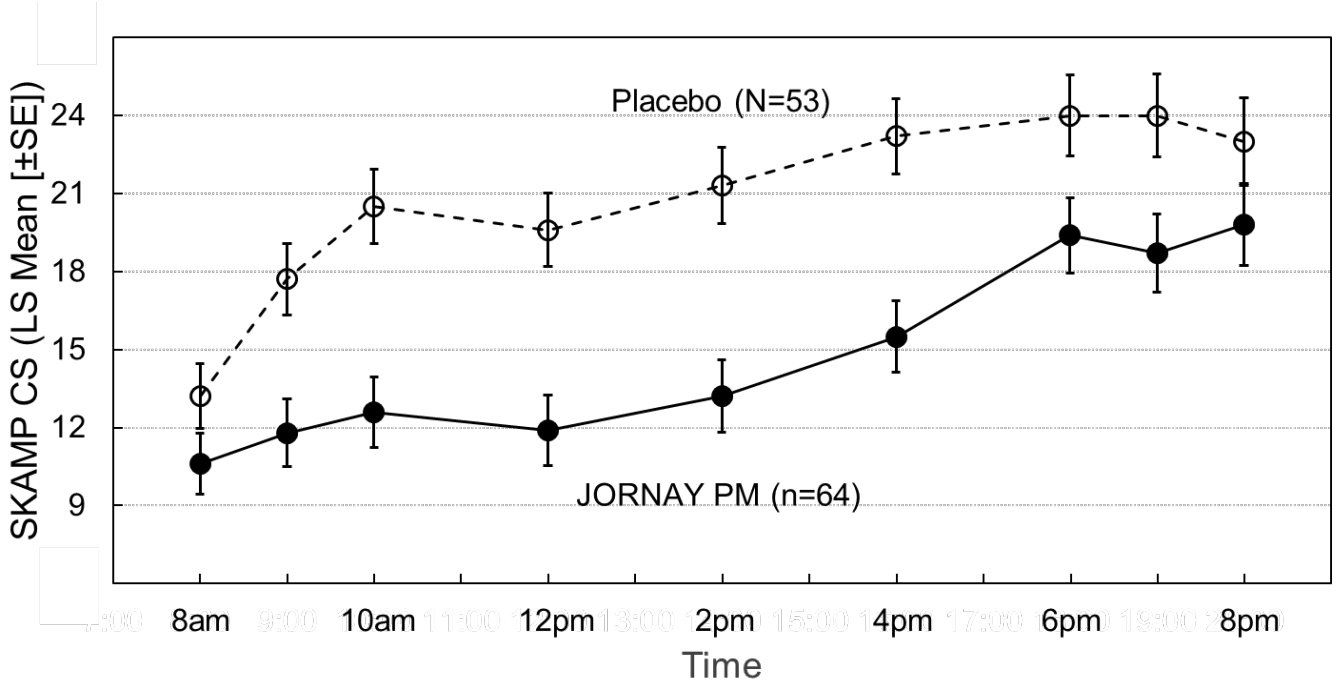
Table 2 summarizes the primary endpoint results for Study 1 and Study 2.

Table 2: Summary of Primary Efficacy Results in Pediatric Patients (6 – 12 years old) with ADHD (Studies 1 and 2)

Study Number.	**Measure** (Primary Endpoint)	Treatment Group (#ITT Subjects)	Mean Baseline Score (SD)	LS Mean (SE)	Placebo-subtracted Difference (95% CI)
Study 1	**SKAMP CS Average**	JORNAY PM (64)	NA	14.8 (1.17)	-5.9 (-9.1, -2.7)
		Placebo (53)	NA	20.7 (1.22)	
Study 2	**ADHD-RS-IV**	JORNAY PM (81)	43.1 (7.33)	24.1 (1.50)	-7.0 (-11.4, -2.7)
		Placebo (80)	43.5 (6.84)	31.2 (1.60)	

ITT: Intent-to-treat. SE: Standard Error. SD: Standard Deviation. CI: Confidence Interval. NA: Not Available.
CS: Combined Score (sum of items 1-13)

Figure 2: Study 1—LS Mean SKAMP Combined Score on Day after Final Treatment, as Measured in an Analogue Classroom in Pediatric Patients (6 to 12 years old) with ADHD, N=117



LS = Least Squares; CS = Combined Score (sum of items 1-13); N= Sample Size; SE = Standard Error

16 HOW SUPPLIED/STORAGE AND HANDLING

JORNAY PM (methylphenidate hydrochloride) extended-release capsules are available as follows:

20 mg Capsules – ivory opaque body and light green opaque cap (imprinted with “20 mg” in black on the body and “IRONSHORE” in black on the cap)
Bottles of 100.....NDC 71376-201-03
40 mg Capsules – ivory opaque body and blue-green opaque cap (imprinted with “40 mg” in black on the body and “IRONSHORE” in black on the cap)

Bottles of 100.....……NDC 71376-202-03
60 mg Capsules – white opaque body and powder blue opaque cap (imprinted with “60 mg” in black on the body and “IRONSHORE” in black on the cap)
Bottles of 100.....……NDC 71376-203-03
80 mg Capsules – white opaque body and light blue opaque cap (imprinted with “80 mg” in black on the body and “IRONSHORE” in black on the cap)
Bottles of 100.....…… NDC 71376-204-03
100 mg Capsules – white opaque body and dark blue opaque cap (imprinted with “100 mg” in black on the body and “IRONSHORE” in white on the cap)
Bottles of 100.....……NDC 71376-205-03

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) *[see USP Controlled Room Temperature]*. Protect from humidity.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Abuse, Misuse, and Addiction

Educate patients and their families about the risks of abuse, misuse, and addiction of JORNAY PM, which can lead to overdose and death, and proper disposal of any unused drug *[see Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2,), Overdosage (10)]*. Advise patients to store JORNAY PM in a safe place, preferably locked, and instruct patients to not give JORNAY PM to anyone else.

Dosage and Administration Instructions

Advise patients that JORNAY PM is taken once daily in the evening. Advise patients that JORNAY PM should not be taken in the morning. It should be taken consistently, either with food or without food, and patients should establish a routine pattern of administration time.

For patients who take JORNAY PM sprinkled over applesauce, the contents of the entire capsule should be consumed immediately; it should not be stored. Patients should take the applesauce with sprinkled beads in its entirety without chewing. When initiating treatment with JORNAY PM, provide dosage escalation and administration instructions *[see Dosage and Administration (2.3)]*.

Advise patients that if they forget to take JORNAY PM at their regularly scheduled time, they may take it as soon as they remember that same evening. If a patient remembers the following morning that they forgot to take their JORNAY PM dose the evening before, advise the patient to wait until their next scheduled evening administration.

Risks to Patients with Serious Cardiac Disease

Advise patients that there are potential risks to patients with serious cardiac disease, including sudden death, with JORNAY PM use. Instruct patients to contact a healthcare provider immediately if they develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease *[see Warnings and Precautions (5.2)]*.

Increased Blood Pressure and Heart Rate

Advise patients that JORNAY PM can cause elevations in blood pressure and heart rate *[see Warnings and Precautions (5.3)]*.

Psychiatric Adverse Reactions

Advise patients that JORNAY PM, at recommended doses, can cause psychotic or manic symptoms, even in patients without a prior history of psychotic symptoms or mania *[see Warnings and Precautions (5.4)]*.

Priapism

Advise patients, caregivers, and family members of the possibility of painful or prolonged penile erections (priapism). Instruct the patient to seek immediate medical attention in the event of priapism *[see Warnings and Precautions (5.5)]*.

Circulation Problems in Fingers and Toes [peripheral vasculopathy, including Raynaud's phenomenon]

- Instruct patients about the risk of peripheral vasculopathy, including Raynaud's phenomenon, and associated signs and symptoms: fingers or toes may feel numb, cool, painful, and/or may change from pale, to blue, to red.
- Instruct patients to report to their physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes.
- Instruct patients to call their physician immediately with any signs of unexplained wounds appearing on fingers or toes while taking JORNAY PM.
- Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients *[see Warnings and Precautions (5.6)]*.

Suppression of Growth in Pediatric Patients

Advise patients, caregivers, and family members that JORNAY PM can cause slowing of growth and weight loss *[see Warnings and Precautions (5.7)]*.

Increased Intraocular Pressure (IOP) and Glaucoma

Advise patients that IOP and glaucoma may occur during treatment with JORNAY PM *[see Warnings and Precautions (5.9)]*.

Motor and Verbal Tics, and Worsening of Tourette's Syndrome

Advise patients that motor and verbal tics and worsening of Tourette's Syndrome may occur during treatment with JORNAY PM. Instruct patients to notify their healthcare provider if emergence of new tics or worsening of tics or Tourette's syndrome occurs *[see Warnings and Precautions (5.10)]*.

Alcohol Effect

Advise patients to avoid alcohol, while taking JORNAY PM. Consumption of alcohol while taking JORNAY PM may result in a more rapid release of the dose of methylphenidate *[see Clinical Pharmacology (12.3)]*.

Pregnancy Registry

Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to JORNAY PM during pregnancy *[see Use in Specific Populations (8.1)]*.

Packaged by:
Patheon Puerto Rico, Inc.
Manatí, Puerto Rico, 00674

Manufactured for:
Ironshore Pharmaceuticals Inc.
Morrisville, NC 27560

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.

JORNAY PM is not recommended for use in children under 6 years of age with ADHD.**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.

    o swallow **all** the applesauce and medicine mixture right away

    o **do not** chew the applesauce and medicine mixture

    o **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:

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

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

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

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.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 09/2025