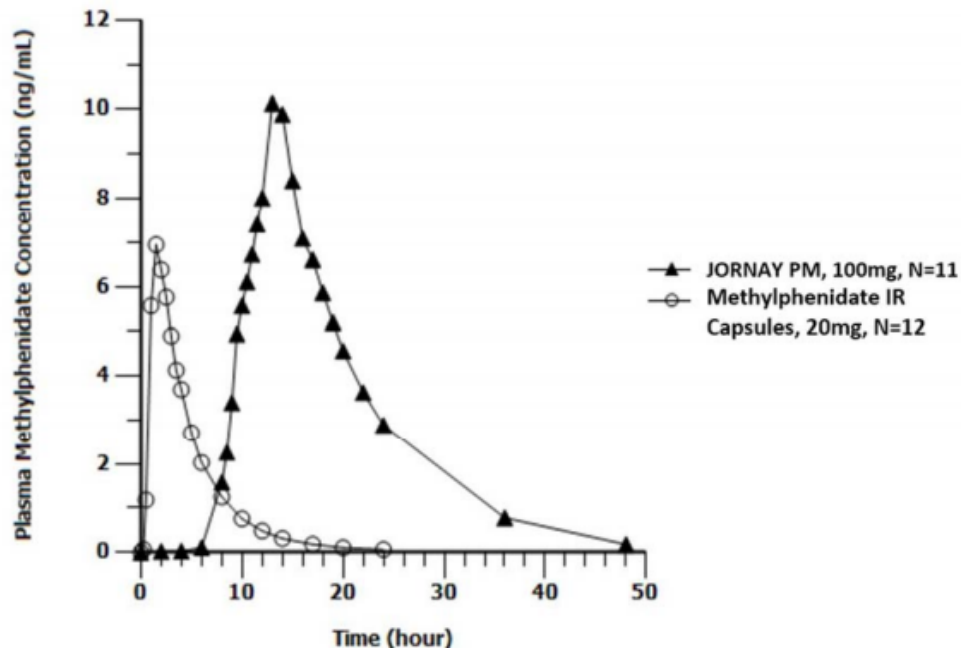


Figure 1: Arithmetic Mean Plasma Methylphenidate Concentrations following a Single, Oral, 100 mg Dose of JORNAY PM (Methylphenidate Hydrochloride Extended-Release Capsule) or Methylphenidate Immediate-Release Oral Product Administered in a Crossover Manner to Healthy Adult Subjects



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.

Mechanism of action: Methylphenidate hydrochloride is a central nervous system (CNS) stimulant.

FDA-approved uses: ADHD in patients 6 years and above

Dosing and formulation: The recommended starting dose of JORNAY PM for patients 6 years and older is 20 mg once daily in the evening. The dose may be titrated weekly in increments of 20 mg. Daily doses above 100 mg have not been studied and are 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.

Patients are advised to take JORNAY PM consistently either with food or without food. Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce.

Extended-Release Capsules: 20 mg, 40 mg, 60 mg, 80 mg, and 100 mg.

Duration of clinical action: Steady state: 14 days with oral dosing (based on 15mg and 30mg trials) 99% protein bound Metabolism/Elimination. After the lag period, the absorption of methylphenidate occurs in a single peak with a median Tmax 14.0 hours, followed by a gradual decline throughout the rest of the day.

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

Common side effects: • decreased appetite • stomach pain • irritability • trouble sleeping • weight loss • mood swings (affect liability) • nausea • anxiety • increased heart rate • vomiting • dizziness • increased blood pressure • indigestion

Warnings and precautions: • Drug Dependence • Hypersensitivity to methylphenidate or other components of the JORNAY PM • Hypertensive crisis when used concomitantly with monoamine oxidase inhibitors • Serious Cardiovascular Reactions • Blood Pressure and Heart Rate Increases • Psychiatric Adverse Reactions • Priapism • Peripheral Vasculopathy, including Raynaud's Phenomenon • Long-term Suppression of Growth

References:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209311s000lbl.pdf

http://online.lexi.com.proxy.lib.mcw.edu/lco/action/doc/retrieve/docid/patch_f/7281?cesid=9jnrJmbYzOR&searchUrl=%2Ffco%2Faction%2Fsearch%3Fq%3Djornay%26t%3Dname%26va%3Djornay