Jornay PM™ (methylphenidate) – New drug approval

- On August 9, 2018, Ironshore Pharmaceuticals announced the FDA approval of Jornay PM (methylphenidate) extended-release capsules for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.

- Methylphenidate is a Schedule II controlled substance and is also available generically as an extended release capsule, oral solution, extended release tablet, chewable tablet, and an immediate release tablet.

    - The orally extended release capsule is approved for ADHD.
    - The oral solution, extended release tablet, chewable tablet, and immediate release tablet are approved for ADHD and narcolepsy.

- The efficacy of Jornay PM was established in two placebo-controlled clinical studies conducted in 278 pediatric patients aged 6 to 12 years with a diagnosis of ADHD. Both studies demonstrated improvements in ADHD symptoms with Jornay PM vs. placebo.

- Similar to other central nervous system stimulants, Jornay PM carries a boxed warning for potential abuse and dependence.

- Jornay PM is contraindicated in patients with known hypersensitivity to methylphenidate or product components and in patients receiving concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days.

- Warnings and precautions of Jornay PM include serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, priapism, peripheral vasculopathy including Raynaud's phenomenon, and long-term suppression of growth.

- The most common adverse reactions (≥ 5% and twice the rate of placebo) with methylphenidate use for pediatric patients and adults are: decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.

- Additional adverse reactions (≥ 5% and twice the rate of placebo) with methylphenidate use in pediatric patients 6 to 12 years of age include headache, psychomotor hyperactivity, and mood swings.

- The recommended dosage 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 8.00pm. Adjust the timing of administration between 6:30 pm and 9:30 pm 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 pm, with an allowed range between 6:30 pm and 9:30 pm. Following determination of the optimal administration time, advise patients to maintain a consistent dosing time.
    - Patients who miss their dose of Jornay PM at the regular scheduled time should take it as soon as they remember that same evening. If the patient remembers the missed dose the following morning, they should skip the missed dose and wait until their next schedule evening dose.

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- Jornay PM should be taken consistently with or without food.

- Ironshore pharmaceuticals plans to initiate the commercial launch of Jornay PM in the first half of 2019. Jornay PM will be available as 20 mg, 40 mg, 60 mg, 80 mg and 100 mg extended- release capsules.

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