

## Cotempla XR-ODT<sup>™</sup> (methylphenidate) – New drug approval

- On June 19, 2017, <u>Neos Therapeutics</u> announced the FDA approval of <u>Cotempla XR-ODT</u> (<u>methylphenidate</u>) extended-release orally disintegrating tablets for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age.
- Cotempla XR-ODT is a schedule II controlled substance.
- According to the Centers for Disease Control and Prevention, ADHD is a common neurodevelopmental disorder of childhood and can continue through adolescence and adulthood. It affects 5% of children and 2.5% of adults in the U.S. Symptoms include inattentiveness, hyperactivity and impulsiveness.
- The approval of Cotempla XR-ODT was supported by a phase 3 clinical trial of 87 children with ADHD in a laboratory classroom setting. Treatment with Cotempla XR-ODT showed a statistically significant improvement in ADHD symptom control vs. placebo across the classroom day (placebosubtracted difference of -11 [95% CI: -13.9, -8.2]).
- Similar to other methylphenidate-containing products, Cotempla XR-ODT carries a boxed warning for abuse and dependence.
- Cotempla XR-ODT is contraindicated in patients with known hypersensitivity to methylphenidate or other components of Cotempla XR-ODT and as concomitant treatment with monoamine oxidase inhibitors (MAOIs), or use of an MAOI within the preceding 14 days.
- Other warnings and precautions with Cotempla XR-ODT 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.
- Based on accumulated data from other methylphenidate products, the most common (> 5% and twice the rate of placebo) adverse reactions with Cotempla XR-ODT use are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- The recommended starting dose of Cotempla XR-ODT is 17.3 mg once daily in the morning.
  - The Cotempla XR-ODT dose may be titrated weekly in increments of 8.6 mg to 17.3 mg.
    Daily doses above 51.8 mg have not been studied and are not recommended.
  - The Cotempla XR-ODT dose should be individualized according to the needs and responses of the patient.
- Neos Therapeutics plans to launch Cotempla XR-ODT in the fall of 2017. Cotempla XR-ODT will be available as 8.6 mg, 17.3 mg and 25.9 mg extended-release orally disintegrating tablets.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.