Cotempla XR–ODT
(methylphenidate)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Cotempla XR-ODT
- **Generic name:** Methylphenidate
  Pharmacological class: CNS stimulant
- **Strength and Formulation:** 8.6mg, 17.3mg, 25.9mg; ext-rel orally disintegrating tabs
- **Manufacturer:** Neos Therapeutics
- **How supplied:** Blister pack—30 (5x6)
- **Legal Classification:** CII

Indications

- Attention deficit hyperactivity disorder

Dosage & Administration

- Place tab on tongue and allow it to disintegrate; do not chew or crush
- Individualize
- **6–17 yrs:** initially 17.3mg once daily in the AM
- May titrate in increments of 8.6–17.3mg weekly; max 51.8mg daily
- Discontinue if no improvement seen after dose adjustment over 1 month

Considerations for Special Populations

- **Pregnancy:** CNS stimulants may cause vasoconstriction and thereby decrease placental perfusion
- **Nursing mothers:** Monitor infants
- **Pediatric:** <6yrs: not established
- **Elderly:** Not studied in patients over the age of 65 years

Contraindications

- During or within 14 days of MAOIs

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 heart rhythm abnormalities, coronary artery disease, other cardiac problems

Warnings/Precautions

- Pre-existing psychotic disorder
- Bipolar disorder
- Screen for risk factors in developing a manic episode prior to initiating
- Consider discontinuing if psychotic/manic symptoms occur
- Peripheral vasculopathy, including Raynaud’s phenomenon; monitor digital changes

Warnings/Precautions

- Monitor growth (in children), BP, HR
- Reduce dose or discontinue if paradoxical aggravation of symptoms occur
- Reevaluate periodically

Interactions

- See **Contraindications**
- Concomitant gastric pH modulators (eg, omeprazole, famotidine, sodium bicarbonate): not recommended

Adverse Reactions

- Appetite decreased
- Insomnia
- Nausea
- Vomiting
- Dyspepsia
- Abdominal pain
- Weight decreased
- Anxiety
- Dizziness
- Irritability
- Affect lability
- Tachycardia
- BP increased
- Priapism

Mechanism of Action

- Methylphenidate is a **CNS stimulant**
- The mode of therapeutic action in ADHD is not known

Clinical Studies

- Cotempla XR-ODT was evaluated in a laboratory classroom study conducted in 87 pediatric patients (aged 6 to 12 years) with ADHD

Clinical Studies

- Following washout of previous methylphenidate medication, there was an open-label dose-optimization period (4 weeks) with an initial dose of 17.3mg of Cotempla XR-ODT once daily in the AM
- Dose could be titrated on a weekly basis up to 51.8mg until an optimal dose or the maximum dose of 51.8mg/day was reached

Clinical Studies

- At the end of this period, patients remained on their optimized dose for an additional week
- They then entered a 1-week randomized, double-blind, parallel group treatment period with the individually optimized dose of Cotempla XR-ODT or placebo

Clinical Studies

- **Primary efficacy endpoint:**
  - Average of the SKAMP-Combined (Attention and Deportment) scores over the test day with assessments conducted at baseline, and 1, 3, 5, 7, 10, 12, and 13 hours post-dosing

Clinical Studies

- The SKAMP-Combined scores test day average was statistically significantly lower (improved) with Cotempla XR-ODT vs. placebo (14.3 vs. 25.3)
  - Placebo-subtracted difference -11.0 (95% CI: -13.9, -8.2)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/cotempla-xr-odt/drug/34708/