Vraylar

(cariprazine)

New Product Slideshow

MPR

Introduction

- **Brand name:** Vraylar
- **Generic name:** Cariprazine
- **Pharmacological class:** Atypical antipsychotic
- **Strength and Formulation:** 1.5mg, 3mg, 4.5mg, 6mg; capsules
- **Manufacturer:** Actavis
- **How supplied:** Bottle—30, 90; Blister packs—7 (1.5mgx1 + 3mgx6)
- **Legal Classification:** Rx

VRAYLAR


Rx Only
NDC 61874-130-30
Vraylar
(cariprazine) capsules
3 mg per capsule
30 Capsules

Indications

- Treatment of **schizophrenia**
- Acute treatment of manic or mixed episodes associated with **bipolar I disorder**

Dosage & Administration

- **Schizophrenia:** initially 1.5mg once daily; increase to 3mg on Day 2; may further adjust by 1.5mg or 3mg increments based on response and tolerability; max 6mg/day
  - Usual range 1.5–6mg once daily
- **Bipolar mania:** initially 1.5mg once daily; increase to 3mg on Day 2; may further adjust by 1.5mg or 3mg increments based on response and tolerability; max 6mg/day
  - Usual range 3–6mg once daily

Dosage & Administration

- **For both:** initiating a strong CYP3A4 inhibitor while on Vraylar: reduce Vraylar dose by ½
- **Initiating Vraylar while already on a strong CYP3A4 inhibitor:** give 1.5mg on Days 1 and 3 (no dose on Day 2), then 1.5mg daily from Day 4 onward; increase to max 3mg daily
- May need to increase Vraylar dose after withdrawing inhibitor

Considerations for Special Populations

- **Pregnancy:** Risk of extrapyramidal and/or withdrawal symptoms post-delivery in neonates due to exposure during 3rd trimester
- **Nursing mothers:** Consider benefits and potential adverse effects
- **Pediatric:** Not established
- **Geriatric:** Insufficient number studied
- **Hepatic or renal impairment:** Severe impairment: not recommended

Warnings/Precautions

- Elderly with dementia-related psychosis **(not approved use)**; increased risk of death or cerebrovascular events (eg, stroke, TIA)
- **Discontinue** immediately if neuroleptic malignant syndrome is suspected; treat appropriately
- Tardive dyskinesia
- Diabetes
- Monitor for hyperglycemia, hyperlipidemia; do fasting blood glucose and lipids testing initially and during therapy

Warnings/Precautions

- Monitor for weight gain, extrapyramidal symptoms, akathisia; consider reducing dose or discontinuing
- Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline
- Hypovolemia
- Dehydration

Warnings/Precautions

- Cardio- or cerebrovascular disease
- Monitor HR and BP
- History of seizures
- Strenuous exercise
- Exposure to extreme heat
- Risk for aspiration
- Reevaluate periodically

Interactions

- See Adults
- Potentiated by strong **CYP3A inhibitors** (eg, itraconazole, ketoconazole)
- Concomitant **CYP3A4 inducers** (eg, rifampin, carbamazepine): not recommended
- Potentiates antihypertensives
- Caution with drugs that interfere with temperature regulation (eg, anticholinergics)

Adverse Reactions

- Extrapyramidal symptoms
- Akathisia
- Dyspepsia
- Vomiting
- Somnolence
- Restlessness
- Dizziness
- Headache
- Constipation
- Abdominal pain
- Nausea
- Diarrhea
- Weight gain
- Fatigue
- Fever
- Tachycardia
- Orthostatic hypotension
- Hyperglycemia
- Dysphagia
- Others

Mechanism of Action

- The efficacy of cariprazine could be mediated through a combination of partial agonist activity at central dopamine D_2 and serotonin 5-HT_{1A} receptors and antagonist activity at serotonin 5-HT_{2A} receptors

Pharmacokinetics

- **Distribution:** Highly bound (91–97%) to plasma proteins
- **Metabolism:** CYP3A4 (major)
- **Elimination:** Renal

Clinical Trials

- The efficacy of Vraylar for the treatment of schizophrenia was established in three, 6-week, randomized, double-blind, placebo-controlled trials in patients who met the DSM-IV-TR criteria for schizophrenia

Clinical Trials

- An active control arm consisting of risperidone or aripiprazole was included in two trials to assess assay sensitivity
- The **primary endpoint** was change from baseline in PANSS total score at the end of Week 6
- Across all 3 trials, Vraylar was superior compared to placebo

Clinical Trials

- The efficacy of Vraylar in the acute treatment of bipolar mania was established in three, 3-week, placebo-controlled trials in patients who met the DSM-IV-TR criteria for bipolar I disorder with mania or mixed episodes with or without psychotic features
- The **primary endpoint** was decrease from baseline in YMRS total score at the end of Week 3
- Across all 3 trials, Vraylar was superior compared to placebo
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the complete product monograph available at:

  http://www.empr.com/vraylar/drugproduct/415/