Inbrija (levodopa)

NEW PRODUCT SLIDESHOW
Introduction

- **Brand name:** Inbrija
- **Generic name:** Levodopa
- **Pharmacological class:** Dopamine precursor
- **Strength and Formulation:** 42mg; per capsule; dry powder for oral inhalation
- **Manufacturer:** Acorda Therapeutics
- **How supplied:** Caps (w. inhaler)—60, 92
- **Legal Classification:** Rx
Inbrija

Inbrija (levodopa inhalation powder)

For Oral Inhalation Only

42 mg capsules

CONTENTS:

Do not swallow Inbrija™ capsules

Inbrija™ capsules are for use with Inbrija™

Do not swallow

CONTENTS:

42 mg capsules
Indication

- Intermittent treatment of OFF episodes in patients with *Parkinson's disease* treated with carbidopa/levodopa
Dosage & Administration

- For oral inhalation only; use with Inbrija inhaler
- **Do not** swallow caps
- Inhale contents of 2 caps (84mg) as needed, up to 5 times daily
  - Max dose per OFF period: 84mg
  - Max daily dose: 420mg
Considerations for Special Populations

- **Pregnancy**: No adequate data on developmental risk associated with use
- **Nursing mothers**: Consider benefits of breastfeeding with potential adverse effect on infant
- **Pediatric**: Not established
- **Elderly**: Some age-related differences in adverse reactions observed
Contraindications

- During or within 14 days of nonselective MAOIs (eg, phenelzine, tranylcypromine)
Warnings/Precautions

- **Sleep disorders**: consider discontinuing if significant daytime sleepiness occurs
- **Withdrawal-emergent hyperpyrexia or confusion**: avoid rapid dose reduction, withdrawal of, or changes in dopaminergic therapy
- Increased risk of **hallucinations** and psychosis
Warnings/Precautions

- Major psychotic disorder, asthma, COPD, chronic lung disease: **not recommended**
- **Impulse control disorders:** consider discontinuing if occurs
- **Glaucoma:** monitor IOP
Interactions

- See Contraindications
- Orthostatic hypotension with MAO-B inhibitors; monitor
- Antagonized by dopamine D2 receptor antagonists (eg, phenothiazines, butyrophenones, risperidone, metoclopramide), isoniazid, iron salts; monitor
- May cause false (+) plasma/urine results suggesting pheochromocytoma
Adverse Reactions

- Cough
- Nausea
- Upper respiratory tract infection
- Sputum discolored
- Dyskinesia (adjust doses)
- CNS disturbances (eg, hallucinations, confusion, somnolence)
- Bronchospasm
- Increased IOP
- Lab abnormalities
Mechanism of Action

- Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier and presumably is converted to dopamine in the brain.
- This is thought to be the mechanism whereby levodopa relieves symptoms of Parkinson’s disease.
Clinical Studies

- The safety and efficacy of Inbrija were evaluated in a 12-week, randomized, placebo-controlled, double-blind study (Study 1) in 226 patients with Parkinson’s disease treated with oral carbidopa/levodopa.
  - Study patients were given Inbrija 84mg or placebo up to 5 times daily.
The **primary endpoint** was the change in Unified Parkinson’s Disease Rating Scale (UPDRS) Part III motor score from pre-dose OFF state to 30 minutes post-dose, measured at week 12.
At week 12, the reduction in UPDRS Part III motor score was **-9.8** for Inbrija vs **-5.9** for placebo, at 30 minutes post-dose (difference -3.92, 95% CI, -6.84, -1.00; \( P = .009 \))
Clinical Studies

- The proportion of patients who returned to an ON state and sustained that ON through 60 minutes post-dose was 58% for Inbrija vs 36% for placebo ($P = .003$)
Clinical Studies

- The effect of Inbrija on pulmonary function in Parkinson’s disease patients was evaluated in a 12-month, randomized, controlled, open-label study (Study 2) in 398 patients
  - Patients with COPD, asthma, or other chronic respiratory disease within the last 5 years were excluded
Clinical Studies

- Pulmonary function was measured by spirometry every 3 months in both groups.
- After 12 months, the average reduction in \( \text{FEV}_1 \) from baseline was the same in both groups (-0.1L).

For more clinical trial data, see full labeling.
New Product Monograph

- For more information view the product monograph available at:
  
  https://www.empr.com/drug/inbrija/