Generic Name:
Levodopa inhalation powder
Trade Name:
Inbrija
Company:
Acorda Therapeutics
Notes:

Acorda Therapeutics announced FDA approval of levodopa inhalation powder for intermittent treatment of "off" episodes in people with Parkinson?s disease treated with carbidopa/levodopa.

Off episodes, also known as off periods, are defined as the return of Parkinson?s symptoms that result from low levels of dopamine between doses of oral carbidopa/levodopa, the standard oral baseline Parkinson?s treatment.

Approval was based on a clinical program that included approximately 900 people with Parkinson?s on a carbidopa/levodopa regimen experiencing off periods.

The agent should not be used by patients who take or have taken a nonselective monoamine oxidase inhibitor, such as phenelzine or tranylcypromine, within the last 2 weeks.

Approval was based on SPAN-PD, a Phase III pivotal efficacy trial, a 12-week, randomized, placebo-controlled, double-blind study evaluating the effectiveness of levodopa inhalation powder in patients with mild to moderate Parkinson?s experiencing off periods.

The SPAN-PD trial met its primary endpoint, with patients showing a statistically significant improvement in motor function at the week 12 visit, as measured by a reduction in Unified Parkinson?s Disease Rating Scale (UPDRS) Part III score for levodopa inhalation powder 84 mg (n = 114) compared with placebo (n = 112) at 30 minutes postdose (?9.83 points and ?5.91 points respectively; P = 0.009). Onset of action was seen as early as 10 minutes.

The most common adverse reactions were cough, upper respiratory tract infection, nausea, and discolored sputum.

The agent was also studied in a Phase III long-term, active-controlled, randomized, open-label study (N = 398) assessing safety and tolerability over 1 year. This study showed the average reduction in FEV1 (forced expiratory volume in 1 second) from baseline was the same (?0.1 L) for the levodopa inhalation powder and observational cohorts.

Patients with COPD, asthma, or other chronic respiratory disease within the last 5 years were excluded from this study.

Levodopa inhalation powder is expected to be commercially available by prescription in the United States in the first quarter of 2019 and will be distributed through a network of specialty pharmacies.

Medication Monitor Categories:
Supplemental Approvals