

## HALLUCINATIONS AND DELUSIONS

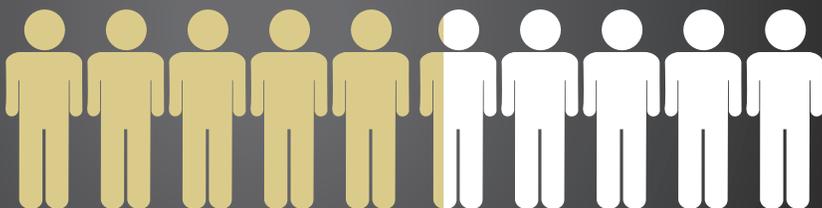


What if your spouse of more than fifty years suddenly started seeing black cats or other animals in the house or unexpected groups of children?<sup>i</sup> Or what if he or she were convinced that someone was stealing his or her life savings from your home computer?<sup>ii</sup> Hallucinations and paranoid delusions commonly develop in adults living with Parkinson's disease.

### What is Parkinson's disease psychosis?

Parkinson's disease psychosis (PD psychosis) is a common condition among patients with Parkinson's disease and is characterized by hallucinations and delusions.<sup>iii</sup> Hallucinations are more common and are often visual.<sup>ii</sup> Delusions often involve suspicions of spousal infidelity or other paranoid themes and may become disturbing and debilitating to patients.<sup>i</sup> PD psychosis contributes to the burden of Parkinson's disease and can affect the quality of life for patients.<sup>iv</sup> It is also associated with increased caregiver burden and is a major reason for nursing home placement among Parkinson's patients.<sup>v, vi</sup>

Parkinson's disease affects about one million people in the United States.<sup>vii</sup> An estimated 40 percent of these patients have Parkinson's disease psychosis, with lifetime prevalence in excess of 50 percent.<sup>iviii</sup> The onset of hallucinations and delusions in Parkinson's patients generally occurs in more advanced stages of the disease.<sup>viii</sup>



PD psychosis develops in greater than

**50%**

of patients over the lifetime of their disease

### Important Safety Information and Indication for NUPLAZID™ (pimavanserin) tablets

#### **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

**QT Interval Prolongation:** NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics.

See additional Important Safety Information on pages 2 and 3



only

10 to 20%

REPORT SYMPTOMS



**Only 10–20 percent of patients will report their psychosis symptoms spontaneously,** possibly because they are embarrassed or because they do not associate them with Parkinson’s disease.<sup>ix,x</sup>

### What causes PD psychosis?

Though the hallucinations and delusions associated with Parkinson’s disease were historically thought to be a side effect of dopaminergic therapy, a causal relationship has not been established.<sup>ii</sup> PD psychosis may be related to progression of the underlying disease.<sup>ii</sup>

### How is PD psychosis treated?

The NUPLAZID™ (pimavanserin) tablet is the only medication approved by the U.S. Food and Drug Administration (FDA) for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis. In a pivotal Phase III clinical trial of 199 patients with PD psychosis (the -020 Study), NUPLAZID was statistically more efficacious than placebo in decreasing the frequency and severity of hallucinations and delusions.<sup>xi</sup>

### What is Parkinson’s disease?

Parkinson’s disease is a chronic and progressive neurodegenerative disorder characterized by the loss of dopamine-producing brain cells. Common motor symptoms include tremors, limb stiffness, slowness of movement, and impaired balance and coordination.<sup>vii</sup>

### Learn More

For more information about Parkinson’s disease psychosis call the National Parkinson Foundation at **1.800.4PD.INFO** or visit <http://www.parkinson.org/understanding-parkinsons/non-motor-symptoms/Psychosis>.

### Contacts:

ACADIA Pharmaceuticals Inc.  
Lisa Barthelemy, Investor Relations  
(858) 558-2871

Taft and Partners  
Ted Deutsch, Media Relations  
(609) 578-8765

### Important Safety Information and Indication for NUPLAZID™ (pimavanserin) tablets (continued)

NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

**Adverse Reactions:** The most common adverse reactions ( $\geq 2\%$  for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).

## Important Safety Information and Indication for NUPLAZID™ (pimavanserin) tablets (continued)

**Drug Interactions:** Strong CYP<sub>3A4</sub> inhibitors (eg, ketoconazole) increase NUPLAZID concentrations. Reduce the NUPLAZID dose by one-half.

Strong CYP<sub>3A4</sub> inducers may reduce NUPLAZID exposure, monitor for reduced efficacy. Increase in NUPLAZID dosage may be needed.

**Renal Impairment:** No dosage adjustment for NUPLAZID is needed in patients with mild to moderate renal impairment. Use of NUPLAZID is not recommended in patients with severe renal impairment.

**Hepatic Impairment:** Use of NUPLAZID is not recommended in patients with hepatic impairment. NUPLAZID has not been evaluated in this patient population.

**Pediatric Use:** Safety and efficacy have not been established in pediatric patients.

**Dosage and Administration:** Recommended dose: 34 mg per day, taken orally as two 17 mg tablets once daily, without titration.

### INDICATIONS AND USAGE

NUPLAZID is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

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- iii Goldman J, Christina V, Goetz C. An update expert opinion on management and research strategies in Parkinson's disease psychosis. *Expert Opin Pharmacother*. 2011
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- ix Fenelon G, Alves G. Epidemiology of psychosis in Parkinson's disease. *J Neural Sci*. 2010
- x Goetz CG, Fan W, Leurgans S, et al. The Malignant Course of Benign Hallucinations in Parkinson Disease. *Arch Neurol*. 2006
- xi Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomized, placebo-controlled phase 3 trial. *Lancet*. 2014