BEYOND MOTOR *symptoms*

Focusing on Parkinson's disease psychosis in the long-term care setting

Points to Consider When Using NUPLAZID® (pimavanserin) 34 mg in a Nursing Facility

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.**

Per Centers for Medicare & Medicaid Services (CMS) guidelines, gradual dose reduction (GDR) may be clinically contraindicated for psychotropics used to treat enduring and progressive conditions such as Parkinson's disease (PD) psychosis.[1]

- NUPLAZID 34 mg is the only FDA-approved therapy proven to reduce delusions and hallucinations associated with PD psychosis in elderly patients without impacting motor function[2]
- In F758 of the *State Operations Manual* for long-term care facilities, CMS defines PD psychosis as an enduring and progressive condition[1]
  - This section also states that attempts at GDR may be clinically contraindicated for progressive and enduring conditions[1]
- When a GDR is clinically contraindicated, facility staff should document that[1]
  - Reducing the psychotropic dose may result in a recurrence of symptoms
  - Continued psychotropic use is in accordance with relevant standards of care
  - The resident is being monitored for potential adverse events

The therapeutic dose of NUPLAZID is 34 mg taken orally once daily, with or without food, without titration.[2]

- NUPLAZID does not require a dosage adjustment in elderly patients, in patients with mild to severe renal impairment or end stage renal disease (ESRD), or in patients with hepatic impairment[2*]
- The recommended dose of NUPLAZID when coadministered with strong CYP3A4 inhibitors (e.g., ketoconazole) is 10 mg, taken orally as one tablet once daily[2]
- Concomitant use of NUPLAZID with strong or moderate CYP3A4 inducers reduces NUPLAZID exposure. Avoid concomitant use of strong CYP3A4 inducers (e.g., carbamazepine, St. John's wort, phenytoin, rifampin) or moderate CYP3A4 inducers (e.g., modafinil, thioridazine, efavirenz, nafcillin) with NUPLAZID[2]
- Avoid the use of NUPLAZID in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval[2]

*Increased exposure (C_{max} and AUC) to NUPLAZID occurred in patients with severe renal impairment (CrCl <30 mL/min, Cockcroft-Gault) in a renal impairment study. NUPLAZID should be used with caution in patients with severe renal impairment and ESRD.[2]

See additional Important Safety Information, including **Boxed WARNING**, on page 2. Please read the full Prescribing Information.

Ensure the diagnosis of PD psychosis is documented in the medical record.[1]

- Diagnostic coding must be to the highest level of specificity, and all coding decisions are ultimately the responsibility of each prescribing health care professional

  ICD-10-CM coding combinations that are recognized for PD psychosis include diagnosis code G20 (for PD) plus one of the following[3]:
  - **F06.0**—Psychotic disorder with hallucinations due to known physiological condition
  - **F06.2**—Psychotic disorder with delusions due to known physiological condition

Review the CMS *State Operations Manual* for long-term care facilities for complete information on psychotropic prescribing, monitoring, and documentation in long-term care facilities.[1]

Ensure residents are prescribed the only FDA-approved treatment for delusions and hallucinations associated with PD psychosis[2]

NUPLAZID 34 mg reduces the frequency and/or severity of PD-related delusions and hallucinations with no impact on motor function[2,4]

NUPLAZID 34 mg: One small capsule, one daily dose[2†]

NUPLAZID is covered on 100% of Medicare Part D Plans[5]

†Actual size is 14.3 mm × 5.3 mm.

Indication

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

Important Safety Information for NUPLAZID (pimavanserin)

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- **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.**

- **Contraindication:** NUPLAZID is contraindicated in patients with a history of a hypersensitivity reaction to pimavanserin or any of its components. Rash, urticaria, and reactions consistent with angioedema (e.g., tongue swelling, circumoral edema, throat tightness, and dyspnea) have been reported.

- **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.
  - 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 (≥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%).

- **Drug Interactions:**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole) increases NUPLAZID exposure. Reduce NUPLAZID dose to 10 mg taken orally as one tablet once daily.
  - Coadministration with strong or moderate CYP3A4 inducers reduces NUPLAZID exposure. Avoid concomitant use of strong or moderate CYP3A4 inducers with NUPLAZID.

Please read the accompanying Prescribing Information, also available at NUPLAZIDhcp.com

References: 1. Centers for Medicare & Medicaid Services. State Operations Manual Pub. 100-07. Appendix PP – Guidance to Surveyors for Long Term Care Facilities. Baltimore, MD: US Dept of Health and Human Services; 2017. **2.** ACADIA Pharmaceuticals Inc. NUPLAZID® [package insert]. San Diego, CA; 2019. **3.** World Health Organization. International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10)-2015-WHO Online Version. http://apps.who.int/classifications/icd10/browse/2015/en. Accessed September 13, 2018. **4.** Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomised, placebo-controlled phase 3 trial. *Lancet*. 2014;383(9916):533-540. **5.** Data on File, ACADIA Pharmaceuticals Inc. March 2018.

ACADIA® Pharmaceuticals

ONCE-DAILY NUPLAZID® (pimavanserin) 34mg capsules