

ONCE-DAILY
NUPLAZID[®]
(pimavanserin) 34mg capsules



PIMA 34
(Not actual size)

SINGLE-CAPSULE DOSING WITH NUPLAZID 34 mg

NUPLAZID[®] (pimavanserin) 34 mg:
One FDA-approved treatment for Parkinson's disease (PD) psychosis,*
one small[†] capsule, one daily dose¹

*NUPLAZID is the only FDA-approved treatment for delusions and hallucinations associated with PD psychosis.¹

[†]Actual size is 14.3 mm × 5.3 mm.

Indication

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

Important Safety Information for NUPLAZID (pimavanserin)

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.

See additional Important Safety Information located throughout.
Please read the full [Prescribing Information](#).

NUPLAZID 34 mg: The single-capsule treatment for Parkinson's disease (PD) psychosis¹

FDA
APPROVED

ONE treatment¹

- The only FDA-approved therapy proven to reduce delusions and hallucinations associated with PD psychosis in elderly patients without impacting motor function
- In the 6-week studies, 80% of patients were aged 65 years or older*



(Not actual size)

ONE small[†] capsule¹

- 34 mg in one single capsule

1
x

ONE daily dose¹

- Taken orally, with or without food
- No dosage adjustment of carbidopa/levodopa is required when administered concomitantly with NUPLAZID

*In clinical trials, the maximum age of patients on NUPLAZID 34 mg was 85 years old vs 90 years old for placebo.²

[†]Actual size is 14.3 mm × 5.3 mm.

Important Safety Information for NUPLAZID (pimavanserin) (cont'd)

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.

See additional Important Safety Information including **Boxed WARNING** located throughout. Please read the full [Prescribing Information](#).

The only FDA-approved treatment for delusions and hallucinations associated with PD psychosis¹

NUPLAZID® (pimavanserin) 34 mg:

- **No impact on motor function¹**
 - NUPLAZID did not impact motor function or motoric activities of daily living*
- **Reduces the frequency and/or severity of PD-related delusions and hallucinations^{1,3}**
 - NUPLAZID showed significant improvement in SAPS-PD at Week 6: 5.79-point reduction vs a 2.73-point reduction with placebo ($P=0.0014$)
- **Demonstrated safety profile in elderly patients with PD psychosis¹**
 - In the 6-week placebo-controlled trials, the most common adverse reactions (incidence $\geq 5\%$ and twice the rate of placebo) were peripheral edema and confusional state
- **A selective serotonin inverse agonist[†]**
 - In vitro, NUPLAZID demonstrated no appreciable binding affinity for dopamine (including D_2), histamine, muscarinic, or adrenergic receptors

Confidently prescribe NUPLAZID 34 mg¹

*As measured by Unified Parkinson's Disease Rating Scale Parts II and III (UPDRS II+III).

[†]The precise mechanism of action of NUPLAZID in the treatment of delusions and hallucinations associated with Parkinson's disease psychosis is unclear. However, the effect of NUPLAZID could be mediated through a combination of inverse agonist and antagonist activity at serotonin 5-HT_{2A} receptors and to a lesser extent at serotonin 5-HT_{2C} receptors.¹

Important Safety Information for NUPLAZID (pimavanserin) (cont'd)

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.

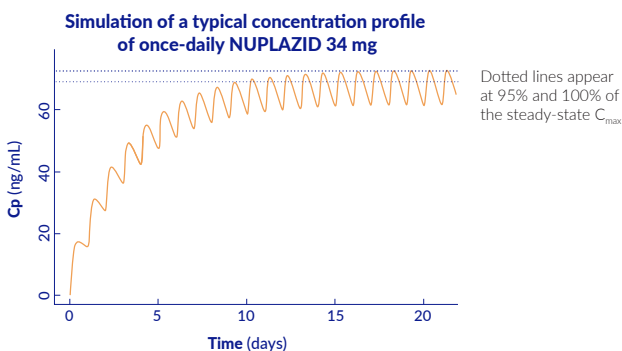
ONCE-DAILY
NUPLAZID®
(pimavanserin) 34mg capsules

NUPLAZID 34 mg: One small* capsule, one daily dose¹

The recommended dose of NUPLAZID is 34 mg, taken orally as one capsule, once daily¹

- No dosage adjustment is required based on age, gender, ethnicity, or weight

The full therapeutic-level steady-state plasma concentration of NUPLAZID 34 mg was reached in 12 days with continuous treatment, without titration^{1,2}



- Half-life ($t_{1/2}$) is 57 hours¹

Dosing and administration considerations¹

- For patients taking a strong CYP3A4 inhibitor, reduce the dosage of NUPLAZID to 10 mg once daily
- For patients taking a strong CYP3A4 inducer, monitor for reduced efficacy and consider increasing dosage of NUPLAZID
- Avoid the use of NUPLAZID in patients with known QT prolongation or in combination with other drugs known to prolong QT interval
- 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†

*Actual size is 14.3 mm × 5.3 mm.

†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.¹

Important Safety Information for NUPLAZID (pimavanserin) (cont'd)

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 CYP3A4 inducers may reduce NUPLAZID exposure. Monitor patients for reduced efficacy and an increase in NUPLAZID dosage may be needed.

Indication

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

Important Safety Information for NUPLAZID (pimavanserin)

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

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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 ($\geq 2\%$ 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%).

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 CYP3A4 inducers may reduce NUPLAZID exposure. Monitor patients for reduced efficacy and an increase in NUPLAZID dosage may be needed.

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

Dosage and Administration

Recommended dose: 34 mg taken orally once daily, without titration.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also call ACADIA Pharmaceuticals Inc. at 1-844-4ACADIA (1-844-422-2342).

NUPLAZID is available as 34 mg capsules, 17 mg tablets and 10 mg tablets. Please read the full [Prescribing Information](#).

ONCE-DAILY
NUPLAZID[®]
(pimavanserin) 34mg capsules

NUPLAZID is affordable and accessible

Comprehensive coverage and financial assistance make NUPLAZID affordable

100%

of Medicare Part D plans cover NUPLAZID⁴

90%

of Medicare Part D patients pay **less than \$25** for their NUPLAZID prescription^{5*}

\$0

copay for commercially covered patients who qualify when enrolled in NUPLAZIDconnect[™]; NUPLAZIDconnect refers patients to independent foundations if they have government insurance

- If patients do not have insurance, or if their insurance does not cover NUPLAZID, they may be eligible to receive NUPLAZID for \$0 through the NUPLAZIDconnect Patient Assistance Program[†]

Prescribing NUPLAZID is simple



- **One-step start**
 - Complete a NUPLAZID treatment form
- Or, prescribe directly to a NUPLAZID in-network specialty pharmacy and use CoverMyMeds[®]



Call **NUPLAZIDconnect**
at **1-844-737-2223**

*Up to 10% of patients may pay more than \$25 for their prescription. As reported by one representative pharmacy organization; 12 months of data.⁵

[†]Other requirements may apply, such as income and US residency.

Important Safety Information for NUPLAZID (pimavanserin) (cont'd)

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 $<1\%$).

See additional Important Safety Information including **Boxed WARNING** on page 5. Please read the full Prescribing Information.

References: **1.** NUPLAZID[®] (pimavanserin) prescribing information, ACADIA. **2.** ACADIA Pharmaceuticals Inc. *NUPLAZID Advisory Committee Briefing Document*. San Diego, CA: Sponsor Background Information for a Meeting of the Psychopharmacologic Drugs Advisory Committee; March 29, 2016. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM492453.pdf>. Accessed June 15, 2018. **3.** 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. **4.** Data on File, ACADIA Pharmaceuticals Inc. March 2018. **5.** Data on File, ACADIA Pharmaceuticals Inc. July 2018.

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