

Nuplazid® (pimavanserin) – New formulation

- On June 29, 2018, <u>Acadia Pharmaceuticals announced</u> the FDA approval of <u>Nuplazid</u>
 (<u>pimavanserin</u>) 34 mg capsules for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
 - Previously, Nuplazid was available as a 17 mg tablet.
- Administration of one 34 mg capsule once daily results in plasma Nuplazid concentrations that are similar to exposure with two 17 mg tablets once daily.
- In addition, a new 10 mg strength tablet will be available to support patients who are concomitantly receiving strong cytochrome 3A4 inhibitors, which can inhibit the metabolism of Nuplazid.
- Nuplazid carries a boxed warning regarding increased mortality in elderly patients with dementiarelated psychosis.
- Other warnings and precautions of Nuplazid include QT interval prolongation.
- The most common adverse reactions (\geq 5% and twice the rate of placebo) with Nuplazid use were peripheral edema and confusional state.
- The recommended dose of Nuplazid is 34 mg orally once daily, without titration.
 - The recommended dose for patients who are concomitantly receiving strong CYP3A4 inhibitors is 10 mg orally once daily.
 - Patients who are concomitantly receiving strong CYP3A4 inducers should be monitored for reduced efficacy of Nuplazid. An increase in Nuplazid dosage may be needed in these patients.
- Acadia plans to launch Nuplazid 34 mg capsules and 10 mg tablets by mid-August 2018. The 34 mg capsules will replace the currently available 17 mg tablets.



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