

- **Nuplazid®**

- Oral capsule: 34 mg
- Oral tablet: 10 mg

If you or someone you know is in crisis, please call 911 and/or the toll-free National Suicide Prevention Lifeline at 800-273-TALK (8255) to speak with a trained crisis counselor 24/7. A help line and other resources are also available through the National Alliance on Mental Illness at nami.org.



What is pimavanserin and what does it treat?

Pimavanserin is a medication that works in the brain to treat hallucinations and delusions associated with Parkinson's disease psychosis. It is also known as a selective serotonin inverse agonist. The exact mechanism in which pimavanserin works to help with Parkinson's disease psychosis is unknown but thought to help with psychosis by blocking certain serotonin receptors.

Symptoms of Parkinson's disease psychosis include:

- Hallucinations – imagined voices or images that seem real
- Delusions - beliefs that are not true (e.g., other people are reading your thoughts)

Pimavanserin may help with some or all of these symptoms.

What is the most important information I should know about pimavanserin?

A person with Parkinson's disease may begin to have delusions or hallucinations. These symptoms may continue to occur throughout the illness. Do not stop taking pimavanserin, even when you feel better.

With input from you, your health care provider will assess how long you will need to take the medication.

Missing doses of pimavanserin may increase your risk for a relapse in your symptoms.

Do not change your dose of pimavanserin without talking to your health care provider.

For pimavanserin to work properly, it should be taken every day as prescribed by your health care provider.

Are there specific concerns about pimavanserin and pregnancy?

Pregnancy is uncommon in people with Parkinson's disease. There is no information on pimavanserin's use in pregnant women that would help predict the risk of serious side effects to an unborn child. If you are planning on becoming pregnant, notify your health care provider to best manage your medications. It is important to discuss the risks and benefits of treatment with your doctor and caregivers. Adverse events were observed in some animal reproduction studies.

There is no information regarding pimavanserin in lactation, therefore, caution should be advised when breastfeeding.

What should I discuss with my health care provider before taking pimavanserin?

- Symptoms of your condition that bother you the most.
- If you have thoughts of suicide or harming yourself.
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects.
- All other medications you are currently taking (including over-the-counter products, herbals, and nutritional supplements) and any medication allergies you may have.
- If you experience side effects from your medications, discuss them with your provider.
- Some side effects may pass with time, but others may require adjustments in the medication.
- Any psychiatric or medical problems you have, such as heart rhythm problems, long QT syndrome (irregular heart beat), or heart attacks.
- If you are pregnant, plan to become pregnant, or are breastfeeding.
- If you smoke, drink alcohol, or use illegal drugs.
- If you have liver disease or kidney disease.

How should I take pimavanserin?

Pimavanserin may help control your symptoms but will not cure your condition.

It may take up to 2 weeks to see significant changes in symptoms.

The recommended dose for pimavanserin is 34 mg once daily with or without food. You may need a lower dose if you take certain medications – check with your doctor or pharmacist.

Use a calendar, pillbox, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member or a friend to remind you or check in with you to be sure you are taking your medication.

What happens if I miss a dose of pimavanserin?

It is important to take your medication everyday as directed by your health care provider. Do not miss or skip a dose.

If you miss a dose of pimavanserin, take it as soon as you remember, unless it is closer to the time of your next dose.

If it is close to the time for your next dose, skip the missed dose and go back to your normal time.

Do not double your dose (e.g., take more than 34 mg total) or take more than prescribed.

What should I avoid while taking pimavanserin?

Avoid drinking alcohol or using illegal drugs while you are taking pimavanserin. They may decrease the benefits (worsen your confusion) and increase adverse effects (sedation, nausea) of the medication.

What happens if I overdose with pimavanserin?

If an overdose occurs call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.

A specific treatment to reverse the effects of pimavanserin does not exist.

What are the possible side effects of pimavanserin?

This is not a complete list. Talk with your health care provider for more information.

Common side effects

Nausea

Rare/serious side effects

Severe dizziness, passing out, fast heartbeat, abnormal heartbeat, swelling in the arms or legs, sensing things that seem real but are not, confusion

Second generation antipsychotics have been linked with higher risk of death, strokes, and transient ischemic attacks (TIAs) in elderly people with behavior problems due to dementia.

All antipsychotics have been associated with the risk of sudden cardiac death due to an arrhythmia (irregular heart beat). To minimize this risk, antipsychotic medications should be used in the smallest effective dose when the benefits outweigh the risks. Your doctor may order an EKG to monitor for irregular heartbeat.

All antipsychotics can cause sedation, dizziness, or orthostatic hypotension (a drop in blood pressure when standing up from sitting or lying down). These side effects may lead to falls which could cause bone fractures or other injuries. This risk is higher for people with conditions or other medications that could worsen these effects. If falls or any of these symptoms occur, contact your health care provider.

Pimavanserin may impair physical or mental abilities; use caution when performing tasks that require mental alertness (e.g., operating machinery, driving).

Allergic reaction is a risk to any component of pimavanserin. The patient should watch for signs of an allergic reaction such as wheezing, chest tightness, itching, swelling of face or lips.

Are there any risks for taking pimavanserin for long periods of time?

None have been reported at this time.

What other medications may interact with pimavanserin?

Tell your health care provider about all medications that you take, have recently taken or plan to take including prescription and nonprescription medications, vitamins, herbal products, and nutritional supplements. This medication may affect the way other medications work, and other medications may affect how this medication works.

The following medications may increase the risk of an arrhythmia (irregular heart beat) when taken with pimavanserin:

- Antipsychotics, including chlorpromazine (Thorazine), thioridazine (Mellaril), asenapine (Saphris), iloperidone (Fanapt), paliperidone (Invega), and quetiapine (Seroquel)
- Antiarrhythmics (heart rhythm medications), including procainamide, quinidine, amiodarone (Cordarone), dronedarone (Multaq), and sotalol (Betapace)
- Antibiotics, including moxifloxacin

The following medications may **increase** the levels and the effects of pimavanserin:

- Itraconazole, Ketoconazole, Clarithromycin, Indinavir

The following medications may **decrease** the levels and the effects of pimavanserin:

- Rifampin, Carbamazepine, Phenytoin, St. Johns Wort

How long does it take for pimavanserin to work?

It is especially important to tell your doctor how you feel things are going during the first few weeks after you start taking pimavanserin. It may take several days to see symptoms improve after you start pimavanserin. It may take up to 2 weeks or longer before you feel the full effect of pimavanserin.

- Hallucinations and delusions may improve in the first 1-2 weeks.
- Sometimes these symptoms do not completely go away.
- Symptoms will continue to get better the longer you take pimavanserin.
- It may take a couple of months before feeling the full benefit of pimavanserin.

Summary of Black Box Warnings

Increased Mortality in Elderly Patients with Dementia Related Psychosis

- Both first generation (typical) and second generation (atypical) antipsychotics are associated with an increased risk of mortality in elderly patients when used for dementia related psychosis.
- Although there were multiple causes of death in studies, most deaths appeared to be due to cardiovascular causes (e.g., sudden cardiac death) or infection (e.g., pneumonia).
- Nuplazid (pimavanserin) is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.