

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Pyridoxine Hydrochloride/Sirolimus

Form: Oral Capsule

Drug Class:

- Pyridoxine Hydrochloride: Vitamin B₆ used for supplementation and managing deficiency.
- Sirolimus: mTOR inhibitor, immunosuppressant (macrolide class) used primarily to prevent organ transplant rejection and to treat certain proliferative disorders.

Mechanism of Action^{1,2,3}:

- Pyridoxine Hydrochloride is intended to:
 - Support cellular metabolism: Functions as a cofactor in amino acid metabolism, neurotransmitter synthesis, and hemoglobin formation.
 - Protect nerves: Helps maintain healthy neuronal signaling, reducing risk of neuropathy from long-term therapies.
- Sirolimus is intended to:
 - Bind FKBP12 and inhibits mTORC1, blocking T- and B-cell proliferation and reducing the burden of senescent cells to potentially suppress inflammatory activation.
 - Reduce cytokine-driven immune responses that would otherwise damage graft tissue to potentially prevent transplant rejection.
 - Inhibit the mTORC1 pathway, slowing down cellular overactivation and senescence, which can help preserve tissue function and delay age-related decline.

Indications Commonly Prescribed for:

- Organ Transplantation (renal, cardiac, hepatic)
- Lymphangioleiomyomatosis (LAM) or PEComa
- Metabolic or cardiovascular risk management in sirolimus patients

Before Use: Let your health care provider know if you have any medication allergies before you take this compounded preparation. Let your health care provider know if you have any liver or kidney problems. Let your healthcare provider know of all supplements you are currently taking.

Contraindications: Known hypersensitivity to ingredients or its derivatives.

Cautions: Let your Healthcare provider know if you experience any adverse side effects.

How to Use: This compounded preparation is in the form of an oral capsule. Swallow the capsule whole with a glass of water. Do not chew or crush the capsule. If you miss a dose, take as soon as you remember, but not at the time for the next dose. Desired results may take up to several weeks.

Warnings and Precautions:

- Pyridoxine HCl: High doses over prolonged periods may cause sensory neuropathy
- Sirolimus: Avoid initiating until graft function is established and surgical wounds are healed.

Compounded medications are not FDA-approved and may differ in risks, benefits, and side effects from FDA-approved products. These statements have not been evaluated by the FDA and are not intended to diagnose, treat or cure any disease or condition and do not indicate any claims of safety or efficacy. Individual results may vary.

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Adverse Reactions:

- Common:
 - Hyperlipidemia, leukopenia, anemia, thrombocytopenia,
 - Delayed wound healing, infections
 - Elevated blood sugar, GI disturbances.
 - Serious, but Rare:
 - Sensory neuropathy with high long-term doses.
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Interactions:

- Enzyme-inducing anticonvulsants (e.g., phenobarbital, phenytoin), and levodopa; can reduce efficacy of pyridoxine or these medications.
 - Inhibitors (e.g., grapefruit, ketoconazole) → increase sirolimus levels (risk of toxicity).
 - Inducers (e.g., St. John's Wort, rifampin) → decrease sirolimus levels (reduced efficacy).
 - Numerous drug interactions with cardio, anticancer, antifungal, and immunosuppressants.
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Use in Specific Populations:

- Pregnancy/Breastfeeding: Use only if clearly needed; sirolimus excreted in milk, and immunosuppression poses risks.
 - Hepatic impairment: Dose reduction recommended in severe liver disease.
 - Renal impairment: Usually no dose adjustment required, but monitor closely.
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Storage:

- Store in original container at room temperature (up to 30°C or 86°F)
 - Store in a cool dry place away from heat, sunlight, and moisture
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Monitoring Parameters:

- Monitor symptom resolution; in high-dose scenarios, assess for neuropathy.
 - Therapeutic drug monitoring: Target trough levels depending on indication (e.g., 16–24 ng/mL first year post-transplant; 5–15 ng/mL for LAM).
 - Laboratory monitoring: CBC (for cytopenias), lipid profiles, glucose, liver function, graft function, signs of infection.
 - Clinical: Wound healing, blood pressure, infection signs, vaccine status.
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Citations:

1. Nelke C, Schroeter CB, Pawlitzki M, Meuth SG, Ruck T. Cellular senescence in neuroinflammatory disease: new therapies for old cells? Trends Mol Med. 2022 Oct;28(10):850-863. doi: 10.1016/j.molmed.2022.07.003. Epub 2022 Aug 12. PMID: 35965205.
 2. Blagosklonny MV. Rapamycin for longevity: opinion article. Aging (Albany NY). 2019 Oct 4;11(19):8048-8067. doi: 10.18632/aging.102355. Epub 2019 Oct 4. PMID: 31586989; PMCID: PMC6814615.
 3. Sahakian V, Rouse D, Sipes S, Rose N, Niebyl J. Vitamin B6 is effective therapy for nausea and vomiting of pregnancy: a randomized, double-blind placebo-controlled study. Obstet Gynecol. 1991 Jul;78(1):33-6. PMID: 2047064.
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