

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Sildenafil Citrate/Tadalafil

Form: Sublingual Rapid Dissolve Tablet

Drug Class:

- Sildenafil Citrate: Phosphodiesterase-5 (PDE5) inhibitor
 - Tadalafil: Phosphodiesterase-5 (PDE5) inhibitor
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Mechanism of Action¹:

- Inhibit phosphodiesterase-5, slowing cGMP breakdown.
 - Maintain cavernosal smooth-muscle relaxation, increase penile blood flow, and improve erectile rigidity.
 - Reduce lower urinary tract smooth-muscle tone supporting BPH symptom relief.
 - Produce systemic vasodilation at varying degrees, affecting BP and vascular beds.
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Indications Commonly Prescribed for:

- Erectile dysfunction (ED)
 - Benign prostatic hyperplasia
 - Pulmonary arterial hypertension
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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:

- Concomitant nitrates or soluble guanylate cyclase stimulators (riociguat).
 - Known hypersensitivity to the drug.
 - Caution or avoidance in significant hypotension, recent MI or stroke, unstable angina, or severe hepatic impairment.
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Cautions: Let your Healthcare provider know if you experience any adverse side effects.

How to Use: This compounded preparation is in the form of a sublingual rapid dissolve tablet. Place tablet under tongue to dissolve completely. Do not chew or crush the capsule. Once the tablet has fully dissolved, do not rinse your mouth, brush your teeth, or consume food or beverages for at least five minutes to allow absorption. If you miss a dose, take as soon as you remember, but not at the time for the next dose. The desired results may take up to several weeks.

Warnings and Precautions:

- Additive vasodilation: Risk of hypotension, dizziness, syncope when used together.
 - Cardiac risk: Both agents increase cardiac workload indirectly through vasodilation; evaluate CV risk before prescribing.
 - Use carefully with alpha-blockers; ensure hemodynamic stability and start PDE5 inhibitor at a low dose.
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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:

- Headache, nasal congestion
- Flushing, dizziness
- Visual hue disturbances

Serious, but Rare:

- Hypotension, syncope
 - Hearing/vision loss
 - Priapism
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Interactions:

- Nitrates and riociguat: contraindicated due to marked BP drop.
 - Alpha-blockers and antihypertensives: additive BP lowering; stabilize alpha-blocker first and use the lowest PDE5 dose.
 - Strong CYP3A4 inhibitors (ketoconazole, itraconazole, clarithromycin, ritonavir): increase exposure; use reduced doses or avoid.
 - CYP3A4 inducers (rifampin, carbamazepine, phenytoin): may reduce efficacy.
 - Alcohol: increases orthostatic hypotension and dizziness.
 - Grapefruit products: may raise levels, especially with tadalafil.
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Use in Specific Populations:

- Pregnancy/Lactation: Contraindicated.
 - Older adults and those with CAD: start low, titrate based on response and tolerability.
 - Renal/Hepatic impairment: prefer specialist input and conservative dosing.
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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:

- Blood pressure and symptoms of dizziness or syncope, especially at initiation or dose change.
 - Efficacy endpoints: erection firmness, time to onset, duration, BPH symptom scores (IPSS) when applicable.
 - Adverse effects: vision or hearing changes, prolonged erection, myalgia/back pain.
 - Drug interaction review at each visit.
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Citations:

1. Mykoniatis I, Pyrgidis N, Sokolakis I, *et al.* Assessment of Combination Therapies vs Monotherapy for Erectile Dysfunction: A Systematic Review and Meta-analysis. *JAMA Netw Open.* 2021;4(2):e2036337. Published online February 18, 2021. doi:10.1001/jamanetworkopen.2020.36337
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