

# PRESCRIPTION MONOGRAPH

---

**Compounded Active Ingredients:** Tadalafil

**Form:** Buccal Troche

---

**Drug Class:** Phosphodiesterase-5 (PDE5) inhibitor

---

## Mechanism of Action<sup>1</sup>:

- Inhibit phosphodiesterase-5, slowing cGMP breakdown to enhance nitric oxide signaling.
  - 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.
- 

## Indications Commonly Prescribed for:

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

**Before Use:** Let your healthcare 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.
- 

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

---

## Warnings and Precautions:

- Additive vasodilation: Risk of hypotension, dizziness, syncope when used together.
  - Cardiovascular risk: Increases 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.
- 

## Adverse Reactions:

Common:

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

Serious, but Rare:

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

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.

# PRESCRIPTION MONOGRAPH

---

## Interactions:

- Nitrates and riociguat: contraindicated due to marked BP drop.
  - Alpha-blockers and antihypertensives: additive hypotension; stabilize alpha-blocker first and use the lowest PDE5 dose.
  - CYP3A4 modulators may alter efficacy
  - Alcohol: increases orthostatic hypotension and dizziness.
  - Grapefruit products: may raise levels, especially with tadalafil.
- 

## 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.
- 

## 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
- 

**How to Use:** This compounded preparation is in the form of a buccal troche. Wash your hands thoroughly. Place the troche gently between your upper gum and cheek—typically on one side of the mouth—and allow it to dissolve naturally. Do not chew, crush, or swallow the troche. Wait an additional 30 minutes before consuming any food or beverages to maximize the amount of medication absorbed through the buccal tissue. 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.

---

## 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.
- 

## Citations:

1. Frajese GV, Pozzi F, Frajese G. Tadalafil in the treatment of erectile dysfunction; an overview of the clinical evidence. *Clin Interv Aging*. 2006;1(4):439-449. doi:10.2147/ciia.2006.1.4.439