# PRESCRIPTION MONOGRAPH

**Compounded Active Ingredients:** Tesofensine
**Form:** Oral Capsule

**Drug Class:** Serotonin–norepinephrine–dopamine reuptake inhibitor (SNDRI), belonging to the phenyltropane family

**Mechanism of Action[1,2]:**
Tesofensine is intended to:

- Inhibit reuptake of serotonin, norepinephrine, and dopamine, increasing their synaptic levels and enhancing signaling in brain regions regulating appetite, mood, and energy balance.
- Modulate lateral hypothalamic activity, particularly by silencing GABAergic neurons, which plays a critical role in suppressing feeding behaviors.

**Indications Commonly Prescribed for:**

- Experimental use in obesity management

**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:**

- Individuals with uncontrolled cardiovascular disease or hypertension, given its potential sympathomimetic effects.
- Patients on serotonergic medications (e.g., SSRIs, SNRIs, MAO inhibitors), as risks of serotonin syndrome may increase.

**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:**

- Cardiovascular effects: May lead to increases in resting heart rate, and at higher doses, can elevate blood pressure. These effects are dose-dependent and require careful monitoring.
- Psychiatric effects: Elevated levels of monoamines may exacerbate anxiety, mood changes, or sleep disturbances.
- Use cautiously in patients with history of arrhythmias, stimulant sensitivity, or serotonergic agent use due to combined risk factors.

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**Adverse Reactions:**

- Common:
  - Constipation, nausea, diarrhea, and GI discomfort
  - Restlessness, mild anxiety, insomnia
  - Headache, dizziness, dry mouth
- Serious, but Rare:
  - Elevated heart rate,
  - Increased blood pressure
  - Palpitations

**Interactions:**

- Serotonergic agents (SSRIs, SNRIs, MAOIs): Risk of serotonin syndrome—caution with concurrent use.
- Sympathomimetic drugs or stimulants: May amplify cardiovascular or mood-related adverse effects.

**Use in Specific Populations:**

- Pregnancy & breastfeeding: No human safety data available; use not recommended.
- Cardiovascular risk patients: High caution or avoidance; monitoring necessary.
- Psychiatric history: Requires careful evaluation due to potential mood effects.
- Pediatrics / Geriatrics: Insufficient data; use not recommended.

**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

**Monitoring Parameters:**

- Vital signs: Monitor heart rate and blood pressure regularly, especially early in therapy or with dose changes.
- Adverse symptoms: Watch for insomnia, dry mouth, GI issues, anxiety, or palpitations.
- Efficacy: Track body weight, BMI, waist circumference, and metabolic markers (e.g., lipids, fasting glucose) where feasible.

**Citations:**


1. Perez CI, Luis-Islas J, Lopez A, et al. Tesofensine, a novel antiobesity drug, silences GABAergic hypothalamic neurons. PLoS One. 2024;19(4):e0300544. Published 2024 Apr 24. doi:10.1371/journal.pone.0300544
2. Axel AM, Mikkelsen JD, Hansen HH. Tesofensine, a novel triple monoamine reuptake inhibitor, induces appetite suppression by indirect stimulation of alpha1 adrenoceptor and dopamine D1 receptor pathways in the diet-induced obese rat. *Neuropsychopharmacology*. 2010;35(7):1464-1476. doi:10.1038/npp.2010.16