

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Oxytocin Acetate/Tadalafil/PT-141

Form: Buccal Troche

Drug Class:

- Oxytocin Acetate: Neuropeptide hormone; Hypothalamic hormone analog
 - Tadalafil: Phosphodiesterase-5 inhibitor; peripheral vasodilator
 - PT-141: Melanocortin-4 receptor agonist
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Mechanism of Action^{1,2,3}:

This compounded combination is intended to address multiple dimensions of sexual function (desire, arousal, and physiological response), by working synergistically between the central and peripheral mechanisms. It is intended to

- Influence the hypothalamus and limbic system to promote sociosexual bonding and reduce anxiety.
 - Activate hypothalamic neurons to improve libido, sexual desire, and emotional arousal.
 - Increase nitric oxide-mediated vasodilation in genital tissues, improving erectile rigidity, genital engorgement, and overall vascular response.
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Indications Commonly Prescribed For:

- Sexual dysfunction and bonding
 - Erectile dysfunction (ED)
 - Sexual performance anxiety
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Before Use: Let your healthcare provider know if you are pregnant or breast feeding. Let your healthcare provider know of all supplements you are currently taking. Let them know of any thyroid or corticosteroid medications you are prescribed.

Contraindications^{1,2,3,4}:

- Hypersensitivity to components
 - Fetal distress, cephalopelvic disproportion (OB use)
 - Cardiovascular disease, uncontrolled hypertension, recent MI or stroke, unstable angina, or severe valvular disease
 - Hyponatremia risk (high doses or prolonged infusion)
 - Nitrates or soluble guanylate cyclase stimulators
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Cautions: Let your Healthcare provider know of any changes of vision while on this compounded preparation.

Warnings and Precautions^{1,2,3,4}:

- Use with caution in patients with seizure disorders
 - Psychiatric effects may be context-dependent (prosocial or defensive)
 - Fluctuations in blood pressure. Monitor with cardiovascular disease
 - Gastroparesis risk: delayed gastric emptying can lead to gastroparesis (stomach paralysis)
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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^{1,2,3,4}: If you experience any side effects or adverse reactions, including those not listed, please contact your healthcare provider. Seek emergency care if symptoms are severe.

Common:

- Nausea, vomiting, diarrhea
- Headache, Dizziness, Fatigue
- Emotional lability, Numbness
- Flu-like symptoms
- Flushing
- Slowed gastric emptying

Serious, but Rare:

- Transient hypertension or decrease heart rate
- Pain (Abdominal/muscle/extremities/joint)
- Restless Leg Syndrome
- Increase creatine phosphokinase
- Focal hyperpigmentation
- Gastroparesis
- Acute hepatitis
- Water Intoxication/hyponatremia
- Hypotension, tachycardia
- Seizures
- NAION

Interactions

^{1,2,3,4}

- May potentiate vasopressin or diuretics
- Caution with SSRIs (risk of hyponatremia)
- Nitrates or riociguat
- Alpha-blockers and antihypertensives
- Strong inhibitors (ketoconazole, clarithromycin, ritonavir) can increase tadalafil exposure
- May alter the absorption of oral medications due to delayed gastric emptying
- Alcohol can increase orthostatic symptoms

Use in Specific Populations:

- Pregnancy: Contraindicated - potential for fetal harm.
- Lactation: It is unknown whether PT-141 is excreted in human milk; caution is advised.
- Pediatrics: Safety and efficacy have not been established in individuals under 18 years of age.
- Geriatrics: Start at lower doses; monitor blood pressure closely.
- Renal impairment: Use with caution - may have an increase in incidence/severity of reactions.
- Hepatic impairment: Use with caution - may have an increase in incidence/severity of reactions.

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.

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Monitoring Parameters:

- Efficacy: Patient-reported desire/arousal, erection quality or genital engorgement, satisfaction
 - Safety: Blood pressure and heart rate around first several doses
 - Serum sodium in patients at risk of SIADH/hyponatremia
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Citations:

1. Olff M, Frijling JL, Kubzansky LD, et al. The role of oxytocin in social bonding, stress regulation, and mental health: an update on the moderating effects of context and interindividual differences. *Psychoneuroendocrinology*. 2013;38(9):1388-1398. doi:10.1016/j.psyneuen.2013.03.011
2. Kingsberg SA, Clayton AH, Portman D, et al. Bremelanotide for the Treatment of Hypoactive Sexual Desire Disorder: Two Randomized Phase 3 Trials. *Obstet Gynecol*. 2019;134(5):899-908. doi:10.1097/AOG.0000000000003500
3. 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
4. Safety information referenced from the FDA-approved labeling for PT-141: U.S. Food and Drug Administration. Vyleesi (bremelanotide) injection, for subcutaneous use: Prescribing information. Silver Spring, MD: FDA; 2019. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/210557s000lbl.pdf. Accessed February 4, 2026.