PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Oxytocin Acetate/Tadalafil/PT-141
Form: Sublingual Rapid Dissolve Tablet

Drug Class:

- Oxytocin Acetate: Neuropeptide hormone; Hypothalamic hormone analog
- Tadalafil: Phosphodiesterase-5 inhibitor; peripheral vasodilator
- PT-14: Melanocortin-4 receptor agonist

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.

Indications Commonly Prescribed For:

- Sexual dysfunction and bonding
- Erectile dysfunction (ED)
- Sexual performance anxiety

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
- Cardiovascular disease, uncontrolled hypertension, recent MI or stroke, unstable angina, or severe valvular disease
- Hyponatremia risk
- Nitrates or soluble guanylate cyclase stimulators

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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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:

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

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
- Alcohol can increase orthostatic symptoms
- May alter the absorption of oral medications due to delayed gastric emptying
- CNS-active drugs (SSRIs/SNRIs)

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 sublingual rapid dissolve tablet. Place tablet under tongue to dissolve completely. Do not chew or crush the tablet. Once the tablet has fully dissolved, do not rinse mouth, brush 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.

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Monitoring Parameters:

- Efficacy: Patient-reported desire/arousal, erection quality or genital engorgement, satisfaction scores
- Monitor for persistent nausea or vomiting, or signs of hypersensitivity reactions.
- Observe for any skin pigmentation changes with prolonged use.
- Safety: Blood pressure and heart rate around first several doses
- Serum sodium in patients at risk of SIADH/hyponatremia

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.