

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
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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:

- 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:

- 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
 - PT-141 can slow gastric emptying and may reduce exposure of time-sensitive oral medications
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Adverse Reactions:

Common:

- Headache
- Emotional lability
- Drowsiness
- Flushing

Serious, but Rare:

- Water Intoxication/hyponatremia
 - Hypotension, tachycardia
 - Seizures
 - NAION
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Interactions:

- 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
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Use in Specific Populations:

- Pregnancy: Contraindicated
 - Geriatrics: Start at lower doses; monitor blood pressure closely.
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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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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 their mouth, brush their 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.

Monitoring Parameters:

- Efficacy: Patient-reported desire/arousal, erection quality or genital engorgement, satisfaction scores
 - 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. Olf 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
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