

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: PT-141 (Bremelanotide Acetate)

Form: Injection

Drug Class:

- Melanocortin-4 receptor (MC4R) agonist
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Mechanism of Action^{1,2}:

- Is intended to activate MC4 receptors in the hypothalamus, which modulate libido and sexual desire
 - Is intended to function independently of nitric oxide pathways—making it effective in central sexual dysfunction
 - Is intended to Increase dopaminergic activity, sexual motivation, and genital arousal in both sexes
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Indications Commonly Prescribed For:

- Hypoactive Sexual Desire Disorder (HSDD) in premenopausal women
 - Low libido or sexual dysfunction in men or women
 - Erectile dysfunction (especially psychogenic)
 - Anorgasmia or delayed orgasm
 - Couples therapy adjunct for intimacy
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Before Use: Let your doctor know if you have had any allergic reactions to injections in the past. Let your health care provider know if you are pregnant or breastfeeding. Let your healthcare provider know of all supplements you are currently taking.

Contraindications:

- Uncontrolled hypertension (PT-141 may increase BP)
 - Hypersensitivity to peptides or excipients
 - History of cardiovascular disease
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Cautions: Take care when injecting the compounded preparation in only specified areas from your health care provider. Check the vial before use for any cloudiness or discoloration before use.

How to Use: This medication is a subcutaneous injection and is delivered in a premixed liquid form. Wash your hands with soap and water before giving the injection. Wipe the rubber stopper of the vial with an alcohol swab. Take a syringe and pull the plunger down to the necessary prescribed amount. This is achieved when the plunger reaches the line for the amount prescribed. Push the needle through the rubber stopper of the vial. Push the plunger down to put air into the vial. Invert the vial and then slowly pull the plunger down past the prescribed dose. If there are bubbles in the syringe, tap the syringe to allow the air bubbles to rise to the top. Slowly push the plunger up until the tip reaches the line for the prescribed dose and removes the bubble of air. Pull the syringe out of the vials rubber stopper. Inject at predetermined injection site as instructed by healthcare practitioner. Discard any remainder from punctured vial after 28 days.

Warnings and Precautions:

- PT-141 can increase blood pressure and heart rate; monitor in patients with cardiovascular risk
- Avoid combining with other serotonergic agents or CNS stimulants unless monitored
- Not evaluated in pregnancy – avoid use unless clearly indicated and supervised

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Adverse Reactions:

- Nausea, vomiting
 - Flushing
 - Headache
 - Transient hypertension
 - Injection site reactions
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Interactions:

- May increase blood pressure and heart rate, counteracting antihypertensive therapies
 - PT-141 may slow gastric emptying, potentially affecting the absorption of oral medications. Caution is advised when co-administering with orally administered drugs that require rapid gastrointestinal absorption.
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Use in Specific Populations:

- Pregnancy: lacks safety data in pregnancy.
 - 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: Permitted with monitoring. Baseline BP and HR should be assessed.
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Storage:

- Refrigerate at 2°C to 8°C (36°F to 46°F)
 - Can be stored at room temperature (up to 30°C or 86°F) for up to 48hrs
 - Do not freeze
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Monitoring Parameters:

- Monitor blood pressure and heart rate before and after administration.
 - Assess for signs of hypersensitivity reactions.
 - Monitor for persistent nausea or vomiting.
 - Observe for any skin pigmentation changes with prolonged use.
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Citations:

1. Heiman JR, Kroll R, Liao X, et al. Effects of Bremelanotide (PT-141) on Sexual Function in Women with Hypoactive Sexual Desire Disorder. J Sex Med. Published 2021. Available from: <https://kinseyinstitute.org/pdf/JSMedicine-heiman%20et%20al.pdf>.
 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
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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.