

PATIENT GUIDE

PT-141 *for men*

A clear look at a medicine that supports sexual response through the brain rather than blood flow: what it is, how it works, what the research in men shows, and how it is used.

COMPOUND	ACTS ON	ROUTE	RESEARCH	SOURCES
Bremelanotide	Brain receptors	Injection	Phase 1 to 2 in men	19 · PMID linked

§ 01

Why we are talking about PT-141

PT-141, known by its generic name bremelanotide, works on sexual response in a way no other approved medicine does. Rather than acting on blood flow in the penis, it acts in the brain, on the pathways that switch on desire and arousal in the first place. That is what makes it interesting for men whose difficulty is not purely mechanical. ¹

This guide explains what PT-141 is, how it works, what the research in men has shown, how it is given, and what your first visit would involve. The research behind it is listed at the end, with links so you can read it yourself.

In the brain	A different mechanism. PT-141 acts on melanocortin receptors in the central nervous system, upstream of the blood flow changes that tablets such as sildenafil support. ²
~30 min	Onset in early studies. In a controlled study in men, the first erection appeared roughly 30 minutes after a dose. The approved injection is taken at least 45 minutes ahead. ^{3 18}
2.7 h	Short acting. The average half life after an injection under the skin is 2.7 hours. It is taken as needed, not every day. ¹⁸
3,500	People in the safety database. The approved product was studied in about 3,500 people across 43 completed studies, which gives a detailed picture of side effects. ⁴

§ 02

What PT-141 is

PT-141 is a small synthetic peptide, seven amino acids joined in a ring. It is modelled on alpha melanocyte stimulating hormone (α -MSH), a hormone your own body makes, and it binds most strongly to the melanocortin 4 receptor, which is involved in sexual function. ¹

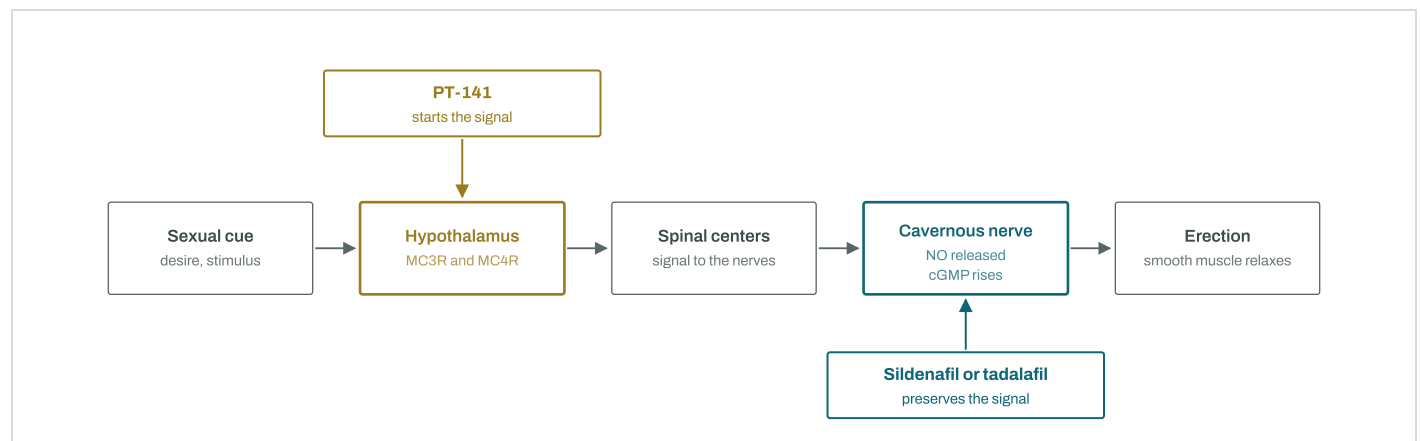
It grew out of research on a related peptide, melanotan II. In a small 1998 study in men with erectile difficulty of no physical cause, melanotan II produced erections in 8 of 10 men, and the time with strong rigidity averaged 38.0 minutes against 3.0 minutes on placebo.⁵ PT-141 was developed from that line of work.

PT-141 AT A GLANCE	
Generic name	Bremelanotide
Approved product	VYLEESI, approved by the FDA in 2019 for a specific condition in premenopausal women ¹⁸
Structure	Ac-Nle-cyclo[Asp-His-D-Phe-Arg-Trp-Lys]-OH
Modelled on	Alpha melanocyte stimulating hormone (α -MSH) ¹
Main target	Melanocortin receptors, especially MC4R, in the brain ^{2 1}
How it is given	Injection under the skin, as needed. Earlier research also used a nasal spray ⁶

§ 03

How PT-141 works

An erection is a chain of events that starts in the brain and ends in the smooth muscle of the penis. Medicines can support that chain at different points, and where a medicine acts decides what it can help with.



The two kinds of medicine act on the same chain at different points. PT-141 works upstream, where arousal begins in the brain. PDE5 tablets work downstream, keeping the signal going once the nerve has fired. This is why PT-141 produced responses in men who responded poorly to sildenafil, and why the two together outperformed sildenafil alone.^{7 8}

The evidence that PT-141 acts centrally is direct. In animal studies it activates neurons in the hypothalamus that connect to the nerves serving the penis.² In healthy men, an injection produced measurable erections even without any visual sexual stimulation, which is not something PDE5 tablets do.⁷

WHY THIS IS USEFUL TO KNOW

If the main difficulty is blood flow, a PDE5 tablet such as sildenafil or tadalafil addresses it directly and is usually tried first. If the difficulty involves desire, getting arousal started, or a limited response to a well dosed tablet, a medicine that acts in the brain addresses a different part of the chain. The two can also be used together under your physician's guidance.⁸

§ 04

What the research shows

What is well established

PT-141 produces erections in men in controlled laboratory studies. In healthy men, doses above 1.0 mg given under the skin produced a significant erectile response, and in men who had an inadequate response to sildenafil 100 mg, both 4 mg and 6 mg doses produced significant responses.⁷ With a nasal spray, responses were significant at doses above 7 mg and began at about 30 minutes.³ In 19 men, a low dose nasal spray combined with 25 mg of sildenafil produced a significantly greater response than sildenafil alone, without new side effects.⁸

The safety profile of the injected product is well characterized, because it was studied carefully for approval in women, including a 52 week extension.⁴⁹ In the two phase 3 trials, 1,267 women were randomized, and those taking bremelanotide had significant increases in sexual desire compared with placebo.¹⁰

What is still being defined

The studies in men are phase 1 and phase 2 studies, most with fewer than 40 participants, and they measured erections with a laboratory device rather than satisfaction at home over months.⁷³ The size of the benefit in the women's trials has also been debated in the literature.¹¹ The use of PT-141 for desire and arousal concerns in men is an active question: a 2026 commentary in the *Journal of Clinical Psychopharmacology* made the case for considering it, and a 2025 review of peptide therapies for erectile dysfunction called for larger trials.¹²¹³ One larger 2008 trial in men is under a formal expression of concern from its journal, so we have not relied on its results.¹⁴¹⁵

STUDIES IN MEN RigiScan is a laboratory device that records rigidity during a visit.

STUDY	N	DESIGN	FINDING
Wessells 1998 melanotan II	10	Double blind crossover, psychogenic erectile difficulty	Erections in 8 of 10 men. Strong rigidity 38.0 versus 3.0 minutes on placebo ⁵
Diamond 2004 nasal spray	n/s	Double blind, placebo controlled, healthy men and mild to moderate difficulty	Significant response above 7 mg, onset about 30 minutes. Flushing and nausea most common ³
Rosen 2004 injection	n/s	Healthy men, then men with inadequate response to sildenafil, crossover	Significant response above 1.0 mg in healthy men, and at 4 mg and 6 mg in sildenafil nonresponders ⁷
Diamond 2005 with sildenafil	19	Randomized crossover	Combination response greater than sildenafil alone, no new side effects ⁸

HOW WE WOULD SUMMARIZE IT

PT-141 works through a well understood pathway in the brain, it produces erections in controlled studies in men, and its side effects are well documented from the approval program. Studies in men are still small, so your physician will talk through where it fits for you, often after or alongside a PDE5 tablet.

§ 05

How PT-141 is given

Injection under the skin

This is the approved route. The injection uses a very small needle in the abdomen or thigh and is taken at least 45 minutes before anticipated activity. The approved product is given as 1.75 mg, no more than one dose in 24 hours, and more than 8 doses a month is not recommended.¹⁸ After an injection, blood levels peak in about an hour.¹⁸ No regulator has set a dose for men; the studies in men used 1 to 10 mg, and your physician sets the dose.⁷

Nasal spray

Much of the early research used a nasal spray, at doses of 7 to 20 mg.³ Blood pressure findings in those earlier nasal studies led developers to move to the injection, which is fully absorbed and associated with fewer side effects.⁶

PRACTICAL PROFILE	
Timing	At least 45 minutes before activity ¹⁸
Onset	About 30 to 60 minutes; blood levels peak at about an hour ^{3 18}
Half life	2.7 hours on average (range 1.9 to 4.0) ¹⁸
Frequency on the approved label	No more than one dose in 24 hours; more than 8 doses a month not recommended ¹⁸
Doses studied in men	1 to 10 mg under the skin; 7 to 20 mg as a nasal spray ^{7 3}

§ 06

What to expect

PT-141 lowers the threshold for arousal. It makes the brain more responsive to a sexual situation rather than producing an erection on its own schedule, so the setting and your partner still matter. Most people take it well ahead of time and then carry on with the evening.

The most common experiences are nausea and flushing, usually within the first hour, and they tend to ease with later doses. In the approval program, nausea was the side effect most likely to lead someone to stop.⁴ A modest, short lived rise in blood pressure is expected after each dose, which is why your blood pressure is checked before you start.^{16 18}

TIPS FROM THE PUBLISHED EXPERIENCE

- Take it at least 45 minutes ahead of time.¹⁸
- Nausea is most common with the first doses; tell your physician if it is bothersome, since the plan can be adjusted.⁴
- Keep to the dosing limits your physician gives you. Frequent dosing is linked to darker patches of skin (see §07).¹⁸

§ 07

Safety

The side effect profile of bremelanotide is well documented from the approval program in women.^{18 4} There were no deaths across the program, and most side effects were mild to moderate.⁴

MOST COMMON SIDE EFFECTS 24 week placebo controlled trials at 1.75 mg, 627 women on bremelanotide and 620 on placebo.¹⁸

SIDE EFFECT	BREMELANOTIDE	PLACEBO
Nausea	40.0%	1.3%
Flushing	20.3%	0.3%
Injection site reactions	13.2%	8.4%
Headache	11.3%	1.9%
Vomiting	4.8%	0.2%

Blood pressure. In an ambulatory monitoring study of 397 women, the 1.75 mg dose raised systolic pressure by about 3 mmHg relative to placebo in the first four hours, with peaks typically lasting under 15 minutes, and heart rate fell by about 4.6 to 4.7 beats per minute.¹⁶ The label describes a maximum rise of 6 mmHg systolic and 3 mmHg diastolic, returning to baseline within 12 hours.¹⁸

Skin darkening. Focal darkening of the skin occurred in about 1 percent of people dosed as labelled, but in 38 percent of people given up to 16 consecutive daily doses.^{18 4} Keeping to the dosing limits matters.

Other points. Bremelanotide lowers blood levels of naltrexone and indomethacin taken by mouth.⁴ A dedicated study in men and women found it safe to take alongside a moderate amount of alcohol, with no meaningful interaction.¹⁷

TELL YOUR PHYSICIAN BEFORE STARTING IF ANY OF THESE APPLY

- You have high blood pressure that is not well controlled, or any known heart or blood vessel disease. These are contraindications on the approved label.¹⁸
- You take nitrates, alpha blockers, naltrexone or indomethacin, or any other prescription medicine.

- You have noticed darker patches of skin, or you have darker skin, since the label notes a higher risk of skin darkening.¹⁸
- You have low testosterone, diabetes, or sleep apnea that has not been treated. These are common, treatable causes of sexual difficulty.

The long term safety data come from women, over up to 76 weeks in total. Long term data in men have not yet been published.⁹

§ 08

Is this right for you

PT-141 suits some men very well and is not the right starting point for others. The purpose of your consultation is to work out which group you are in.

Before we begin

- | | |
|--------------------------|---|
| ☐ | A review of your medical history, current medications and supplements |
| ☐ | Blood pressure and a cardiovascular history, with an ECG if your physician feels one is warranted |
| ☐ | Baseline bloodwork, which usually includes testosterone and metabolic markers |
| ☐ | A clear note of what you are hoping for, written down, so we can tell together whether it worked |

If your bloodwork points to a specific and treatable cause, such as low testosterone or blood sugar that needs attention, we will address that first. Treating the cause is often the most effective step of all.

Reviewing your progress

We will look at how things are going against your starting point after a defined period rather than leaving it open ended. If it is helping, we will plan how to continue. If it is not, we will say so and look at other options. You are welcome to stop at any time.

QUESTIONS WORTH ASKING US

What would you expect me to notice, and by when? Should I try a PDE5 tablet first or alongside it? How will we manage nausea if it happens? What would make you recommend stopping? We are glad to answer all of these.

§ 09

Regulatory status, stated plainly

Bremelanotide is approved by the U.S. Food and Drug Administration as VYLEESI, for acquired, generalized hypoactive sexual desire disorder in premenopausal women. The label states that it is not indicated for men.¹⁸ Use in men is therefore off label. Prescribing an approved medicine off label is lawful and common in American

medicine, and it is a decision your physician makes with you. Specialist societies describe the use of PT-141 in men as off label and still being studied.¹⁹

Preparations used for men are prescribed by your physician and prepared by a licensed pharmacy. If you would like details about the preparation used in your treatment, please ask.

References

Every source below is indexed in PubMed or published by the FDA or a medical society

- 1 **Dhillon S, Keam SJ.** Bremelanotide: first approval. *Drugs.* 2019;79(14):1599-1606. [PMID 31429064](#)
- 2 **Molinoff PB, et al.** PT-141: a melanocortin agonist for the treatment of sexual dysfunction. *Ann N Y Acad Sci.* 2003;994:96-102. [PMID 12851303](#)
- 3 **Diamond LE, et al.** Double-blind, placebo-controlled evaluation of the safety, pharmacokinetic properties and pharmacodynamic effects of intranasal PT-141, a melanocortin receptor agonist, in healthy males and patients with mild-to-moderate erectile dysfunction. *Int J Impot Res.* 2004;16(1):51-59. [PMID 14963471](#)
- 4 **Clayton AH, et al.** Safety profile of bremelanotide across the clinical development program. *J Womens Health (Larchmt).* 2022;31(2):171-182. [PMID 35147466](#)
- 5 **Wessells H, et al.** Synthetic melanotropic peptide initiates erections in men with psychogenic erectile dysfunction: double-blind, placebo controlled crossover study. *J Urol.* 1998;160(2):389-393. [PMID 9679884](#)
- 6 **Edinoff AN, et al.** Bremelanotide for treatment of female hypoactive sexual desire. *Neurol Int.* 2022;14(1):75-88. [PMID 35076581](#)
- 7 **Rosen RC, et al.** Evaluation of the safety, pharmacokinetics and pharmacodynamic effects of subcutaneously administered PT-141, a melanocortin receptor agonist, in healthy male subjects and in patients with an inadequate response to Viagra. *Int J Impot Res.* 2004;16(2):135-142. [PMID 14999221](#)
- 8 **Diamond LE, et al.** Co-administration of low doses of intranasal PT-141, a melanocortin receptor agonist, and sildenafil to men with erectile dysfunction results in an enhanced erectile response. *Urology.* 2005;65(4):755-759. [PMID 15833522](#)
- 9 **Simon JA, et al.** Long-term safety and efficacy of bremelanotide for hypoactive sexual desire disorder. *Obstet Gynecol.* 2019;134(5):909-917. [PMID 31599847](#)
- 10 **Kingsberg SA, et al.** Bremelanotide for the treatment of hypoactive sexual desire disorder: two randomized phase 3 trials. *Obstet Gynecol.* 2019;134(5):899-908. [PMID 31599840](#)
- 11 **Spielmans GI.** Re-analyzing phase III bremelanotide trials for "hypoactive sexual desire disorder" in women. *J Sex Res.* 2021;58(9):1085-1105. [PMID 33678061](#)
- 12 **Pfaus JG, Balon R.** Should bremelanotide be considered for the treatment of sexual arousal and desire disorders in men? *J Clin Psychopharmacol.* 2026;46(3):245-248. [PMID 41960633](#)
- 13 **Ila V, et al.** Intravenous peptides and amino acids for erectile dysfunction: a narrative review of current applications and future directions. *Expert Opin Pharmacother.* 2025;26(5):631-637. [PMID 40069591](#)
- 14 **Safarinejad MR, Hosseini SY.** Salvage of sildenafil failures with bremelanotide: a randomized, double-blind, placebo controlled study. *J Urol.* 2008;179(3):1066-1071. [PMID 18206919](#)
- 15 **Safarinejad MR, Hosseini SY.** Expression of concern: salvage of sildenafil failures with bremelanotide: a randomized, double-blind, placebo controlled study. *J Urol.* 2023 Jan 10; doi:10.1097/JU.0000000000003117. [PMID 36626345](#)
- 16 **White WB, et al.** Usefulness of ambulatory blood pressure monitoring to assess the melanocortin receptor agonist bremelanotide.

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- 17 **Clayton AH, et al.** Phase I randomized placebo-controlled, double-blind study of the safety and tolerability of bremelanotide coadministered with ethanol in healthy male and female participants.
Clin Ther. 2017;39(3):514-526.e14. PMID 28189361
-
- 18 **U.S. Food and Drug Administration.** VYLEESI (bremelanotide injection) prescribing information.
Label revised 2020. accessdata.fda.gov
-
- 19 **Sexual Medicine Society of North America.** Understanding patient perspectives on peptides for treating erectile dysfunction.
SMSNA, June 2026. smsna.org
-



IMPORTANT NOTICE

This document is patient education prepared by Regen Therapy MD. It is not medical advice, not a prescription, and not a promise of any clinical outcome. **Bremelanotide (PT-141) is approved by the U.S. Food and Drug Administration only as VYLEESI, for acquired, generalized hypoactive sexual desire disorder in premenopausal women. Any use in men is off label.** Individual results vary, and no outcome can be predicted from the studies cited here.

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DATE

REVIEWING PHYSICIAN

RTMD-WP-014 · Version 2.0 · 26 September 2026 · Next scheduled literature review: March 2027 · Prepared with sources indexed in PubMed and FDA public records.