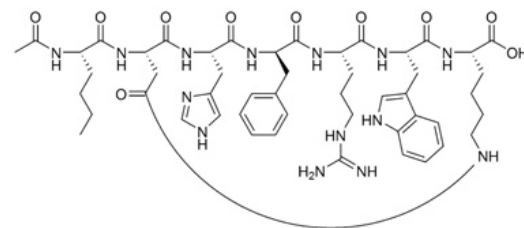




PT-141, 10mg (Bremelanotide) Information



| | |
|------------------------|---|
| <u>Product Name:</u> | PT-141 |
| <u>Unit size:</u> | 10 mg/vial |
| <u>CAS NO.:</u> | 189691-06-3 |
| <u>Synonyms:</u> | PT-141, Bremelanotide |
| <u>Sequence:</u> | Ac-Nle-cyclo(Asp-His-D-Phe-Arg-Trp-Lys-OH) |
| <u>Purity:</u> | ≥98% (HPLC) |
| <u>Physical State:</u> | Lyophilized Powder |
| <u>Solubility:</u> | Soluble in water or 1% acetic acid |
| <u>Storage:</u> | Lyophilized peptides although stable at room temperature for 3 months, should be stored desiccated below -18°C. Upon reconstitution of the peptide it should be stored at 4°C between 2-21 days and for future use below -18°C. |

PT-141 (Bremelanotide) originally developed from the peptide known as Melanotan 2 (MT-II) is the generic term for a new pharmaceutical grade synthetic aphrodisiac research peptide. It has been developed to address Erectile/Sexual Dysfunction or impotence in men, as well as sexual dysfunction in women (sexual arousal disorder). More than 40 per cent of women suffer from 'female sexual dysfunction'. PT-141 is the only synthetic aphrodisiac. Unlike Viagra and other related medications (PDE5s), PT-141 does not act upon the vascular system, but directly through the nervous system (hypothalamus) to increase desire. Viagra, Cialis and Levitra are not considered aphrodisiacs as they do not have any direct effect on the libido. However, treatment with PDE5 inhibitors and PT-141 are known to have a synergistic effect.

Originally, the peptide Melanotan II that bromelanotide was developed from was tested as a sunless tanning agent. In initial testing, Melanotan II did induce tanning but additionally caused sexual arousal and spontaneous erections as unexpected side

effects in eight out of the ten original male volunteer test subjects. In clinical studies, bremelanotide has been shown to be effective in treating male sexual and erectile dysfunction as well as female sexual dysfunction. It is currently being tested by Palatin Technologies (you will find the fact sheet on PT-141 by Palatin Technologies below).

Bremelanotide is a cyclic hepta-peptide lactam analog of alpha-melanocyte-stimulating hormone (alpha-MSH) that activates the melanocortin receptors MC3-R and MC4-R in the central nervous system. It has the amino acid sequence Ac-Nle-cyclo[Asp-His-D-Phe-Arg-Trp-Lys]-OH or cyclo-[Nle4, Asp5, D-Phe7, Lys10]alpha-MSH-(4-10). PT-141 is a metabolite of Melanotan II that lacks the C-terminal amide function. Its molecular formula is C₅₀H₆₈N₁₄O₁₀ with a molecular weight of 1025.2. In the United States it is currently in a Phase III clinical trial.

How does it come?

Bremelanotide PT-141 Peptide comes in 10mg vials. As a lifestyle peptide, the 10mg product is a lot to consume and may offer up to 20 doses when dosing light. The PT-141 peptide reconstituted with bacteriostatic water remains potent in the fridge for months.

Currently the nasal and oral routs have not been made efficient and any nasal sprays, pre-mixed PT-141, pills and loose powder are not legitimate. There are successful reports of snorting and nasal spray experiences...however they are few and far between. PT-141 is a sterile injectable made for sub-q injection (like insulin).

DOSING

0.30 mg (trial)

0.70 mg (average)

1 mg (optimal)

1.5 mg (strong)

2mg (extra strong)

Bremelanotide is injected (subcutaneously) and opens a window of possibilities, desire, and strength for you a couple of hours later. PT 141 has a unique window of opportunity lasting six to 72 hours and should be administered 2-4 hours before you are wanting to feel the effects of the peptide.

Does this help give erections or just put you in the mood?

With PT-141, you feel good, not only sexually aroused," reported anonymous patient 007, a participant in a Phase 2 trial, "you feel younger and more energetic." Said another patient: "It helped the libido. So you have the urge and the desire. . . . You get this humming feeling; you're ready to take your pants off and go." And another:

“ Twice my wife and I had sex twice in one night. I came in [to work] and I just raved about it: ‘ Jesus, guys . . . 58 years old and you don’ t do that.’ ” Tales of pharmaceutically induced sexual prowess among 58-year-olds are common enough in the age of the Little Blue Pill, but they don’ t typically involve quite so urgent a repertoire of humming, throbbing, tingling, and double-dipping. Or as patient 128 put it: “ My wife knows. She can tell the difference between Viagra and PT-141.”

The precise mechanisms by which PT-141 does its job remain unclear, but the rough idea is this: Where Viagra acts on the circulatory system, helping blood flow into the penis, PT-141 goes straight to the brain itself. And there it goes to work, switching on the same neural circuitry that lights up when a person actually, you know, wants to.

Basically this takes men back to middle school. You may find yourself in a similar situation as you were in 8th grade science class with the teacher bent over helping the student in front of you. It may be necessary to do a “ tuck up” if at the office...especially at the public pool!

Women state that the sensation given from injecting PT-141 is like being in heat! One colleague in particular stated that she didn’ t know what was going on...but she had wanted “ it” all day long after dosing the night before.

Is there any reconstituting involved?

Yes

Bacteriostatic water is the recommended mixing product however this product is a prescription only product and hard to get. You can currently purchase it on eBay for around \$30 a vial however sterile water can be used.

To mix the vial with bac water, take one syringe and grab your vial of bacteriostatic water. If using a 1 cc syringe (100 units), use the syringe to withdraw 1 full ml (1cc) and inject that into the vial of PT-141 through the rubber. Be sure to aim the needle towards the glass, so that it will trickle down and not harm the peptide. Swirl the vial to thoroughly mix and let the peptide dissolve. The key here is to be gentle.

If you have your vial of PT-141 stored in the freezer, move the vial of PT-141 to fridge the night before you plan on reconstituting it so that when you mix it it is the same temperature refrigerated bac water with the PT-141 which is the most efficient manner. Just some tricks of the trade here!

So now you have 100 units (1cc) of bacteriostatic water mixed with 10 mg of PT-141 in your vial ready to go. A 1mg dose would be 10 units or .1ml (.1cc). Make sense? Hope so.

PT141 reconstituted with bacteriostatic water remains preserved for 6-12 months and

a month in the refrigerator when mixed with sterile water before it begins to degrade. We recommend preloading your syringes and storing them in the freezer if you are reconstituting with sterile water instead of bac water.

How should PT-141 stored?

Vials are freeze-dried and therefore will remain stable at room temperature for 1-2 months. However, for long-term storage they should be stored in the freezer, where they will remain stable for up to 24 months in powder form. Once mixed with it should be stored in the fridge and not left at room temperature! It will last 1 month if you have reconstituted with sterile injectable water and 6-12 months if you have used bacteriostatic water. We recommend preloading your syringes if you are using sterile injectable water and freezing them. This will prolong the life of your PT-141. DO NOT preload if you are using bac water.

FOR RESEARCH PURPOSES ONLY

Disclaimer: All peptides are sold for research and laboratory use only. This product is not for human consumption. This product can be harmful if ingested and buying these products also means that the buyer acknowledges the hazards that could potentially occur with the use of these products. This product is not intended to prevent, treat, or cure disease conditions or to affect the structure or function of the body.

Hush Hushhh (hush-hushhh.com) takes no responsibility for harm caused from melanotan if used for purposes other than research and laboratory use.

Please pursue information regarding the usage of Melanotan II from your own research, academic journals, or the research of your in-house scientific team.

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PT-141 Fact Sheet



PALATIN
TECHNOLOGIES, INC.

A Novel Drug Candidate for the Treatment of Sexual Dysfunction in Both Men and Women

PT-141: FIRST IN CLASS THERAPY

PT-141, the first in a new class of therapies called melanocortin agonists, works through a mechanism of action involving the central nervous system rather than directly on the vascular system. As a result, it may offer significant safety and efficacy benefits over currently available products, including Viagra®, Levitra® and Cialis®, which belong to the class of phosphodiesterase-5 (PDE-5) inhibitors.

PT-141 is nasally administered and is both non-invasive and fast acting. Importantly, PT-141 is not expected to be contraindicated in patients taking nitrates for the treatment of cardiovascular disease. Clinical studies have demonstrated PT-141 to be safe and effective and to improve patient experience.

PT-141 IN THE CLINIC

PT-141 has been evaluated in four Phase 2 efficacy studies enrolling more than 300 men. Study data have been presented at several scientific conferences and PT-141 has been the topic of numerous journal articles.

PT-141 in Men:

- effective in a broad range of patients, including those with severe ED and those non-responsive to sildenafil
- efficacy in "at-home" studies is comparable to PDE-5 inhibitors
- up to 50% of ED patients were restored to a normal level of function
- co-administration with sildenafil shows superior efficacy
- side effects include facial flushing, nausea, aftertaste and post-nasal drip

PT-141 in Women:

Palatin conducted a Phase 2A study in 18 premenopausal women with a diagnosis of female sexual dysfunction (FSD). Patients reported a significant increase in sexual desire and in genital arousal after receiving PT-141, compared to placebo. Additionally, there was a correlation between sexual desire and genital arousal in patients receiving PT-141, an observation that further reinforces the potential importance of these reports.

Additional Clinical Trials:

Palatin plans to begin Phase 3 trials in men in the second half of 2006. A Phase 2B at-home study of PT-141 in female patients with FSD is planned for the second half of 2005.

Market Opportunity

With more than 30 million men in the U.S. suffering from erectile dysfunction (ED), the ED market is currently valued at over \$2B and is projected to reach \$3B within three years. While statistics for females are not yet well defined, studies show that approximately 50 million women suffer from female sexual dysfunction (FSD), a condition for which there are currently very limited treatment options.



PT-141 VS. PDE-5 INHIBITOR: POSITIVE ATTRIBUTE PROFILE

| Feature | PT-141 | PDE-5 |
|-----------------------------------|----------|----------|
| Initiation of Erection | High | Low |
| Quality of Erection | High | Moderate |
| Duration of Erection | High | Moderate |
| Time to Onset | High | Moderate |
| Cardiovascular Safety | High | Moderate |
| Food Interaction | High | Low |
| Consistency of Efficacious Effect | Moderate | Moderate |
| Tolerability | Moderate | Moderate |
| Route of Administration | Moderate | High |

Source: Internal Market Research, October 2003

ADDRESSING A LARGE MARKET OPPORTUNITY

According to the Massachusetts Male Aging Study, more than 50% of men aged 40 to 70 report periodic episodes of ED and more than 30 million men in the U.S. suffer from ED. Although not inevitable, the incidence of ED does increase with age. Studies show that chronic ED affects about 5% of men in their 40s, and 15-25% of men by the age of 65. Transient ED and inadequate erection affect as many as 50% of men between the ages of 40 and 70.

Diseases (including coronary artery disease, diabetes and hypertension) account for up to 70% of chronic ED cases and psychological factors (e.g., stress, anxiety, depression) may account for up to 10 to 20% of cases. Between 35% and 50% of men with diabetes experience ED.

The first generation of pharmaceutical treatments for ED are PDE-5 inhibitors, of which there are currently three on the market. This class of therapy is mainly focused on the vascular physiology (blood flow) of penile erection. While these therapies are certainly an advancement over mechanical methods, such as vacuum constriction devices or surgically implanted penile prostheses that have been used for decades, PDE-5 inhibitors are not without drawbacks. Among them:

- up to 40% of men don't refill their prescriptions
- 33% of men don't respond to any PDE-5 inhibitor
- contraindications with other medications often preclude PDE-5 inhibitors as potential therapy
- the potential for unsafe cardiovascular effects

A Market Need Exists for ED Products That Are Differentiated by Safety, Efficacy and Improved Patient Experience

STRATEGIC ALLIANCE WITH KING PHARMACEUTICALS

In August 2004, Palatin formed a strategic alliance with King Pharmaceuticals (NYSE:KING) to jointly develop and commercialize PT-141. King's large primary care/cardiovascular-focused sales force makes King an ideal partner for Palatin and PT-141. Palatin will have primary responsibility for preclinical and clinical development and manufacturing, and will have the right to co-promote PT-141 to the urology specialty market. The two companies will jointly seek a marketing partner outside the U.S. The collaboration is potentially worth \$250M in milestone payments to Palatin. Additionally, Palatin and King will share costs and profits on a worldwide basis.



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