**vyleesi®**
(bremelanotide injection)
1.75 mg/0.3 mL | for subcutaneous use only

Vyleesi is the **first and only as-needed** treatment that has been **FDA-approved** for premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD)[1]

GET AN RX ONLINE

# Melanocortin 4 receptor agonism enhances sexual brain processing in women with hypoactive sexual desire disorder

*Thurston L, et al. Journal of Clinical Investigation. 2022;132(19):e152341. doi: 10.1172/JCI152341.*


- A **first-of-its-kind** study exploring the effects of MCR4 agonism on sexual brain processing in premenopausal women with HSDD
- Researchers investigated Vyleesi,[2] a novel FDA-approved melanocortin 4 receptor (MC4R) agonist for the treatment of HSDD in premenopausal women, to **better understand** the effect of MC4R activation on sexual brain activity and behavioral psychometric measures of sexual arousal and desire during visual erotic stimuli
- **Randomized controlled crossover** trial comparing Vyleesi vs placebo employing multiple analyses
- Results presented in this peer-reviewed paper demonstrate the **beneficial impact** of Vyleesi on sexual brain processing and help explain its **mechanism of action** in increasing sexual desire in women with HSDD

## The study demonstrated that compared with placebo, Vyleesi:

Elicited **significant effects** on the brain response to erotic stimuli ($P$<0.05)

**Increased** sexual desire for up to 24 hours post-administration ($P$=0.007)

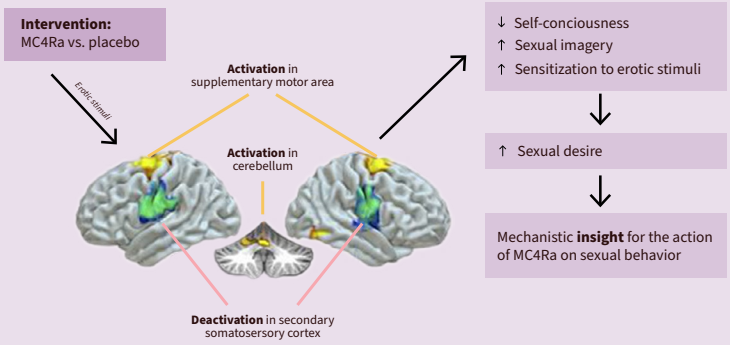
Led to **2.5x** as many women reporting an increase in sexual desire when taking Vyleesi ($P$≤0.01)

**Decreased** food intake and hunger

## fMRI clinical study in HSDD patients illustrated how Vyleesi works in the brain

Psychometric, neuroimaging and hormonal analyses in **31 women** with HSDD

- Melancortin-4 receptor agonism (MC4Ra)
- ↑ Sexual desire




**Activation** of areas with decreased activity in HSDD

- Supplementary motor area (SMA), which **regulates** responses to visual erotic stimuli
- Cerebellum, which is involved in **promoting** sexual arousal regions in the normal response to erotic stimuli

**Deactivation** of secondary somatosensory cortex, restoring responses to sexual stimuli

**Enhanced** functional connectivity between the amygdala and insula and the amygdala and thalamus, important regions in the normal response to erotic stimuli

- The results of this trial were **consistent** with Palatin's preclinical, Phase 2, and Phase 3 trial **results** that support the approval of Vyleesi as the **first and only FDA-approved** as-needed treatment for premenopausal women with HSDD.

CLICK HERE TO ACCESS THE PUBLICATION

Please see full Prescribing Information available at Vyleesipro.com and Important Safety Information on reverse.

PALATIN

## HSDD affects the brain

## &

## Vyleesi affects HSDD

Animal studies have shown melanocortins and Vyleesi **demonstrate effects** on female rats and dopamine release/uptake - *Pfaus et al*

Brain activity in women with HSDD has been shown to be **different** than in those without HSDD. - *Arnow, etc.*

Vyleesi interacts with **important regions** of the brain that have been shown to play a role in the normal sexual response, shown via fMRI study - *Thurston, et al*

Vyleesi development program demonstrated **consistent, robust efficacy** - *Palatin data on file*


# What is hypoactive sexual desire disorder (HSDD)?

HSDD is a **persistent** deficiency of sexual fantasies and desire for sexual activity[2]

Underdiagnosed and undertreated due to **limited options**, many with delays in onset, side effects, and limitations to use

**1/10** Up to 10% of premenopausal women **suffer** from HSDD around the world[2]

MC4R agonists have shown to be **effective** in the treatment of patients with HSDD[3-5]

### IMPORTANT SAFETY INFORMATION

**Do not use Vyleesi if you have:**

- high blood pressure that is not controlled (uncontrolled hypertension)
- known heart (cardiovascular) disease

**Before using Vyleesi, tell your healthcare provider about all of your medical conditions, including if you:**

- high blood pressure.
- have heart problems.
- have kidney problems.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if Vyleesi will harm your unborn baby.
    - Women who can become pregnant should use effective birth control during treatment with Vyleesi.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Vyleesi may affect the way other medicines work, and other medicines may affect the way Vyleesi works.

**How should I use Vyleesi?**

- Inject Vyleesi at least 45 minutes before you think that you will begin sexual activity.
- **Do not** inject more than 1 dose of Vyleesi within 24 hours of your last dose.
- **Do not** inject more than 8 doses of Vyleesi within a month.

**What are the possible side effects of Vyleesi?**

**Vyleesi can cause serious side effects, including:**

- **Temporary increase in blood pressure and decrease in heart rate:** An increase in blood pressure and decrease in heart rate can happen shortly after you inject Vyleesi. These changes usually go away within 12 hours after your injection. Increases in blood pressure and an increased risk of heart (cardiovascular) problems can happen if you use Vyleesi more often than prescribed by your healthcare provider.
- **Darkening of the skin on certain parts of the body (focal hyperpigmentation), including the face, gums (gingiva), and breast.** The chance of darkening of the skin is increased in people with darker skin color. The chance of darkening of the skin is higher if Vyleesi is used every day. Darkening of the skin may not go away, even after you stop using Vyleesi.
- **Nausea.** Nausea is common and can also be severe. Nausea most commonly happens after the first Vyleesi injection but can also happen after any dose of Vyleesi. The nausea usually lasts for about 2 hours but can last longer in some people. The nausea usually goes away by itself. Tell your healthcare provider if you have nausea that is severe or does not go away.

**The most common side effects of Vyleesi include:** flushing, injection site reactions, headache, vomiting, cough, fatigue, hot flush, tingling, dizziness, and nasal congestion. These are not all the possible side effects of Vyleesi.

Call your doctor for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact Palatin Technologies at **1-800-972-5220** or FDA at **1-800-FDA-1088** or **fda.gov/medwatch.**

### INDICATION

**What is Vyleesi?**

Vyleesi is a prescription medicine used to treat hypoactive (low) sexual desire disorder (HSDD) in women who have not gone through menopause, who have not had problems with low sexual desire in the past, and who have low sexual desire no matter the type of sexual activity, the situation, or the sexual partner. Women with HSDD have low sexual desire that is troubling to them. Their low sexual desire is not due to:

- a medical or mental health problem
- problems in the relationship
- medicine or other drug use

Vyleesi is not for the treatment of HSDD in women who have gone through menopause or in men.
Vyleesi is not for use to improve sexual performance.
Vyleesi is not for use in children.

[1] VYLEESI [package insert]. Cranbury, NJ: Palatin Technologies, Inc.; 2021. [2] Thurston L, et al. "Melanocortin-4 receptor agonism enhances sexual brain processing in women with hypoactive sexual desire disorder." Journal of Clinical Investigation. 2022: e152341. [3] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders: DSM-IVTR. American Psychiatric Press. 2000. [4] Kishi T, et al. Expression of melanocortin 4 receptor mRNA in the central nervous system of the rat. J Comp Neurol. 2003;457(3):213–235. [5] Dhillon S, Keam SJ. Bremelanotide: first approval. Drugs. 2019;79(14):1599–1606.



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