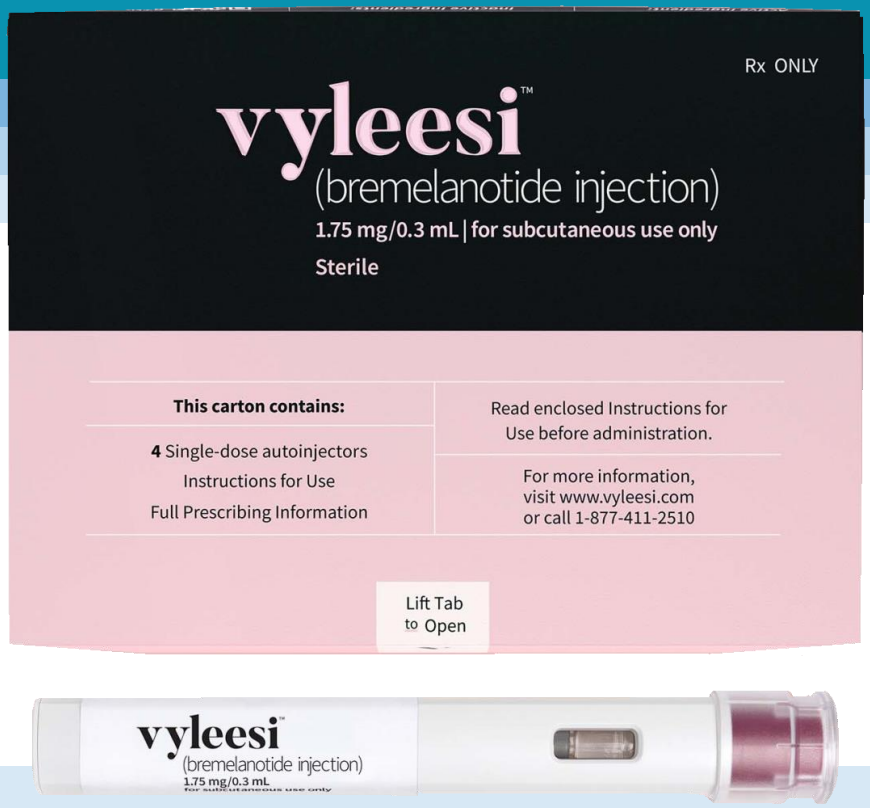
Vyleesi (bremelanotide acetate)



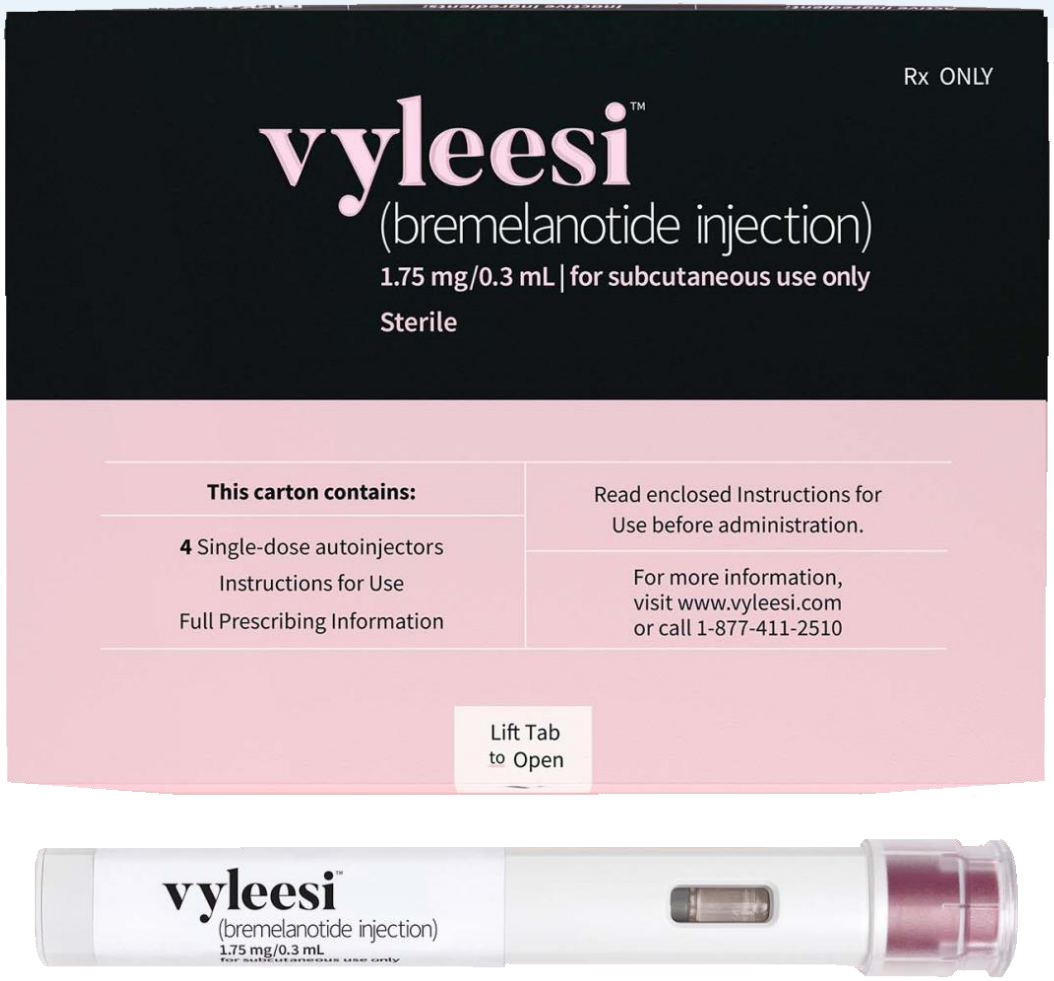
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Vyleesi
- **Generic name:** Bremelanotide acetate
- **Pharmacological class:** Melanocortin receptor agonist
- **Strength and Formulation:** 1.75mg/0.3mL; solution for subcutaneous (SC) injection
- **Manufacturer:** AMAG Pharmaceuticals
- **How supplied:** Single-dose prefilled autoinjectors—4
- **Legal Classification:** Rx

Vyleesi


Rx ONLY
vyleesi™
(bremelanotide injection)
1.75 mg/0.3 mL | for subcutaneous use only
Sterile
This carton contains:
4 Single-dose autoinjectors
Instructions for Use
Full Prescribing Information
Read enclosed Instructions for Use before administration.
For more information, visit www.vyleesi.com or call 1-877-411-2510
Lift Tab to Open
vyleesi™
(bremelanotide injection)
1.75 mg/0.3 mL

Indication

- Treatment of premenopausal women with acquired, generalized **hypoactive sexual desire disorder** (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
  - A co-existing medical or psychiatric condition,
  - Problems with the relationship, or
  - The effects of a medication or drug substance

Limitations of Use

- Not for HSDD in postmenopausal women or in men
- Not for sexual performance enhancement

Dosage & Administration

- Self-administer by SC inj in abdomen or thigh as needed, at least 45mins before sexual activity
- 1.75mg as a single daily dose
- Max 1 dose per 24hrs or 8 doses per month
- Discontinue if no improvement after 8 weeks

Considerations for Special Populations

- **Pregnancy:** not recommended; may be associated with fetal harm based on findings in animal studies
- **Nursing mothers**: no information on the presence of bremelanotide in human milk
- **Pediatric**: not established
- **Geriatric:** not established
- **Renal impairment:** no dosing adjustments needed with mild or moderate impairment; use caution in patients with severe impairment
- **Hepatic impairment:** no dosing adjustments needed with mild or moderate impairment; not evaluated in patients with severe impairment: use caution

Contraindications

- Patients who have **uncontrolled hypertension** or known **cardiovascular disease**

Warnings/Precautions

- Consider patient's **cardiovascular risk** before initiating and periodically during treatment, and ensure BP is well-controlled
  - Vyleesi transiently increases BP and reduces heart rate after each dose
- High risk for cardiovascular disease: not recommended
- Consider discontinuing if hyperpigmentation develops
- Advise females of reproductive potential to use effective contraception while taking Vyleesi, and to discontinue if pregnancy is suspected

Interactions

- Avoid concomitant oral drugs that depend on threshold concentrations for efficacy (eg, antibiotics)
- Consider discontinuing if there is a delayed effect of concomitant oral drug when a quick onset is desired (eg, indomethacin)
- Avoid use with **oral naltrexone-containing products** intended to treat alcohol or opioid addiction

Adverse Reactions

- **Most common** (>4%): nausea, flushing, injection site reactions, headache, vomiting
- **Others**: cough, fatigue, hot flush, paraesthesia, dizziness, nasal congestion; focal hyperpigmentation (esp. with dark skin), transient increases in BP and reduction in HR

Mechanism of Action

- Bremelanotide is a melanocortin receptor (MCR) agonist that nonselectively activates several receptor subtypes with the following order of potency: MC1R, MC4R, MC3R, MC5R, MC2R
- At therapeutic dose levels, binding to MC1R and MC4R is most relevant
- The mechanism by which Vyleesi improves HSDD in women is unknown

Clinical Trials

- The efficacy of Vyleesi was evaluated in 2 identical 24-week, randomized, double-blind, placebo-controlled trials (Study 1 and Study 2) in premenopausal women with acquired, generalized HSDD of at least 6 months (N=1247)
- Patients were randomized 1:1 to either Vyleesi 1.75mg SC injection (n=635) or placebo (n=632) and were instructed to administer the drug at least 45 minutes prior to sexual activity
- Patients were not to exceed more than 1 dose within 24 hours and no more than 12 doses per month

Clinical Trials

- The co-primary efficacy end points for both studies were the change from baseline to end of study (EOS) using the Female Sexual Function Index (FSFI) Desire domain score ranging from 1.2 to 6 (higher scores indicate improvement in sexual desire) and the score for feeling bothered by low sexual desire as measured by the Female Sexual Distress Scale - Desire/Arousal/Orgasm Question 13 (FSDS-DAO Q13) with responses on a scale of 0 (never) to 4 (always) where lower scores indicate improvement in the level of distress

Clinical Trials

- At Week 24, both studies showed a statistically significant increase in the FSFI Desire Domain score and a statistically significant decrease in the FSDS-DAO Q13 score compared with placebo
- Results from Study 1 for the FSFI-Desire Domain score showed a mean change from baseline for Vyleesi of 0.5 compared with 0.2 for placebo (*P* =.0002)
- Study 1 also showed a mean change from baseline of −0.7 for the FSDS-DAO Q13 score compared with −0.4 for placebo (*P* <.0001)

Clinical Trials

- Findings from Study 2 for the FSFI-Desire Domain score demonstrated a mean change from baseline of 0.6 for Vyleesi vs 0.2 for placebo (P <.0001)
- The Vyleesi treatment arm also demonstrated a mean change from baseline of −0.7 for the FSDS-DAO Q13 score versus −0.4 for placebo (P =.0053)
- Moreover, Study 1 and Study 2 investigated the number of satisfying sexual events (SSEs) as a secondary endpoint
- Both studies did not show a significant difference in the number of SSEs between treatment groups in the change from baseline to EOS visit
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/vyleesi/