

PATIENT INFORMATION
VYLEESI® (vahy-lee-see)
(bremelanotide injection)
for subcutaneous use

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.

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:

- have 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.
 - **Pregnancy Registry:** There will be a pregnancy registry for women who use VYLEESI during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry or call the VYLEESI Pregnancy Exposure Registry at 800-922-1038.
 - Women who can become pregnant should use effective birth control during treatment with VYLEESI. Talk to your healthcare provider about birth control choices that may be right for you during this time. Stop using VYLEESI and tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with VYLEESI.
- are breastfeeding or plan to breastfeed. It is not known if VYLEESI passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby if you use 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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use VYLEESI?

See the detailed “Instructions for Use” that comes with VYLEESI for information on how to prepare and inject a dose of VYLEESI. Talk to your healthcare provider or pharmacist if you have any questions.

- Use VYLEESI exactly as prescribed by your healthcare provider.
- VYLEESI comes in an autoinjector that you or your caregiver may use at home to give injections.
- VYLEESI is given as an injection under the skin (subcutaneous injection), in your thighs or stomach area (abdomen).
- 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.

Tell your healthcare provider if your symptoms of HSDD have not improved after you have used VYLEESI for 8 weeks.

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. See **“How should I use VYLEESI?”**
- **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. Tell your healthcare provider if you have any concerns about changes to your skin.

- **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. Your healthcare provider may prescribe an anti-nausea medicine for you.

The most common side effects of VYLEESI include:

- flushing
- vomiting
- hot flush
- nasal congestion
- injection site reactions
- cough
- tingling
- headache
- fatigue
- dizziness

These are not all the possible side effects of VYLEESI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VYLEESI?

- Store at or below 77°F (25°C).
- Do not freeze.
- Protect from light.

Keep VYLEESI and all medicines out of the reach of children.

General information about the safe and effective use of VYLEESI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VYLEESI for a condition for which it was not prescribed. Do not give VYLEESI to other people, even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about VYLEESI that is written for health professionals.

What are the ingredients in VYLEESI?

Active ingredient: bremelanotide

Inactive ingredients: 2.5% glycerin, sterile water for injection, and hydrochloric acid or sodium hydroxide is added to adjust the pH

Marketed By: Cosette Pharmaceuticals, Inc.

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For more information, go to www.VYLEESI.com or call Cosette Pharmaceuticals, Inc. Customer Service at the toll-free number 1-800-922-1038.

This Patient Information has been approved by the U.S. Food and Drug Administration

Revised: 03/2024