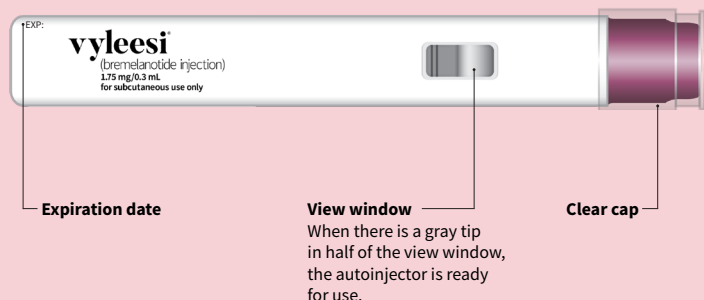
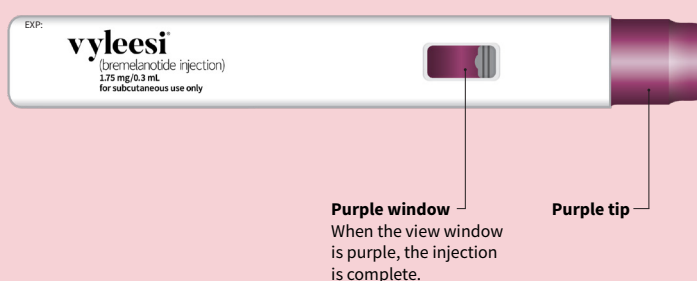


Parts of the Autoinjector

Before Use



After Use



Instructions for Use

Read this Instructions for Use before you use VYLEESI and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. Do not inject VYLEESI unless you have been trained by your healthcare provider. Talk to your healthcare provider or pharmacist if you have any questions.

Important Safety Information

- **Do not** use more than 1 dose of VYLEESI in 24 hours.
- **Do not** use more than 8 doses of VYLEESI within a month.
- **Use 1 autoinjector for your dose of VYLEESI.** Throw away (dispose of) the autoinjector after giving your injection. See Step 6: Throw away (dispose of) the VYLEESI autoinjector.
- **Inject VYLEESI into the skin of the stomach area (abdomen) or thigh only.**
- **Do not** pull off the clear cap from the VYLEESI autoinjector until you are ready to inject VYLEESI.

Storage

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.

Supplies Needed for Your Injection

- 1 alcohol wipe (not included in carton)
- 1 VYLEESI autoinjector
- 1 cotton ball or gauze (not included in carton)
- 1 adhesive bandage (not included in carton)
- 1 sharps disposal container for VYLEESI autoinjector disposal. See Step 6: Throw away (dispose of) the VYLEESI autoinjector.

Read and follow Step 1 to Step 6 to use the VYLEESI autoinjector.

Step 1. Check Supplies



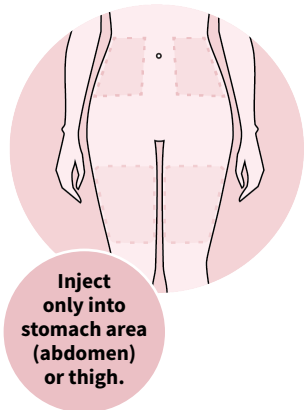
Check the label on the autoinjector for the expiration date (EXP). **Do not** use the autoinjector if the expiration date has passed.

Check the view window. You should see the gray tip in half of the view window and the medicine in half of the view window. If the view window is purple, the autoinjector will not work. Use a new autoinjector if the view window is purple.

Look at the medicine in the view window. It should be clear and free of particles. **Do not** use if the medicine is cloudy, discolored, or contains particles.

Check that the clear cap fits tightly on the purple tip of the autoinjector. If the cap does not fit tightly or is damaged, do not use the autoinjector. Call Palatin Technologies, Inc. at 1-800-972-5220.

Step 2. Get Ready



Wash your hands with soap and water.

Choose an injection site on your stomach area (abdomen) or the front of your thigh. Avoid the area on your abdomen that is 2 inches around your belly button (navel).

- Do not inject into skin that is irritated, sore, bruised, red, hard, or scarred.
- Do not inject through your clothes.
- Choose a different site each time you give yourself an injection.

Clean the injection site with an alcohol wipe.

Let the injection site air dry. Do not fan or blow on the clean area. Do not touch the injection site again before giving the injection.

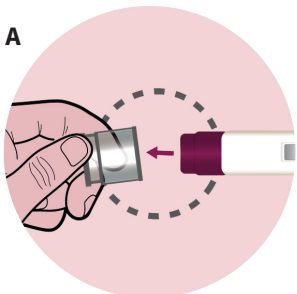
Step 3. Prepare and Give Injection

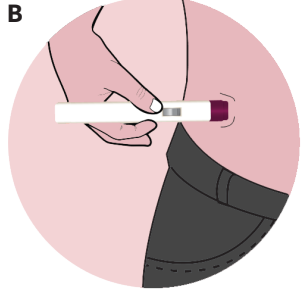
The autoinjector **must be used right away after it is activated.**

Pull the clear cap from the autoinjector (See Figure A) to activate.

- **Do not try to recap** the autoinjector.
- **The autoinjector should be used or thrown away right after the cap is removed.**
See Step 6: Throw away (dispose of) the VYLEESI autoinjector.

(Continued on next page)

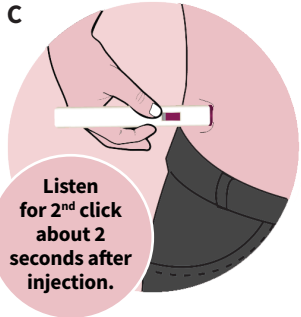




Important: During the injection you will hear **two clicks**.

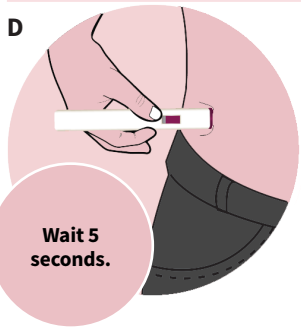
Place the purple tip flat against the center of the clean skin at your injection site.

Make sure you can see the view window (See Figure B).



Press down and hold the autoinjector firmly against your skin (See Figure C). **You will hear the 1st click right away**, which tells you that your injection has started.

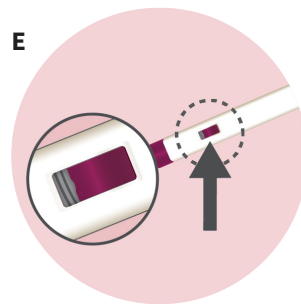
In about 2 seconds, you will hear a **2nd click**.



Continue to press and hold the autoinjector firmly against your skin **for about 5 seconds** after the 2nd click to be sure your injection is complete (See Figure D).

Step 4.

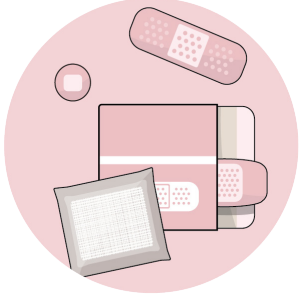
Check that the Medicine was Given



Check that the view window is now purple with a small part of the gray tip still showing. This means that all of the medicine was given (See Figure E).

Remove the autoinjector by **lifting it straight off of your skin**. After you remove the autoinjector from your skin, the purple tip will lock over the needle.

Step 5. Check the Injection Site



- A cotton ball or gauze can be used initially to apply pressure after the injection if there is bleeding. An adhesive bandage should be applied after this, if needed.
- Apply an adhesive bandage if needed.
- **Do not** rub the injection site.

Step 6. Throw away (dispose of) the VYLEESI Autoinjector



Put your used VYLEESI autoinjector in a FDA-cleared sharps disposal container right after use (See Figure F).

Do not throw away (dispose of) the autoinjector in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.

For more information about safe sharps disposal and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.



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