



(dihydroergotamine mesylate)
injection
1 mg/mL
Autoinjector

INSTRUCTIONS FOR USE
BREKIYA® [breh-kee-yah]
(dihydroergotamine mesylate)
injection, for subcutaneous use

This Instructions for Use contains information on how to inject BREKIYA.

If there are any questions concerning the use of BREKIYA autoinjector, ask your healthcare provider, pharmacist or visit www.brekiya.com.

Important Information You Need to Know Before Injecting BREKIYA

Warnings

- BREKIYA is for injection under the skin (subcutaneous) only.
- The rigid needle shield of the BREKIYA autoinjector contains a needle cover (located inside the cap) that contains dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.
- **Do not** remove the red needle cap until you are ready to inject BREKIYA. Inject BREKIYA right away after removing the red needle cap.
- **Do not** inject BREKIYA if the autoinjector appears damaged, if the expiration date has passed, if the liquid medicine is cloudy, discolored or has floating flakes or particles.
- **Do not** throw away (dispose of) the autoinjector into the household trash. Throw away (dispose of) the autoinjector into a FDA-cleared sharps disposal container.

Dosing

- Follow your healthcare provider's dosing instructions for how often to inject BREKIYA autoinjector.
- Each autoinjector contains 1 dose (1 mg) of BREKIYA. After your first dose of BREKIYA, you may give yourself 2 more doses (for a total of 3 mg) as needed. Wait at least 1 hour between doses.
- **Do not** inject more than 3 doses (3 mg) of BREKIYA in 1 day (24-hour) period.
- **Do not** inject more than 6 doses (6 mg) during a 1-week (7-day) period.

Storing BREKIYA Autoinjector

- Store the BREKIYA autoinjector at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect BREKIYA from light.
- Keep BREKIYA in the carton until ready to use.
- **Do not** refrigerate or freeze BREKIYA.

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

Autoinjector Parts

This autoinjector is a prefilled single dose (1 time use), disposable device that gives a 1 mg subcutaneous (under the skin) injection of BREKIYA. Figure A shows a new and used autoinjector.

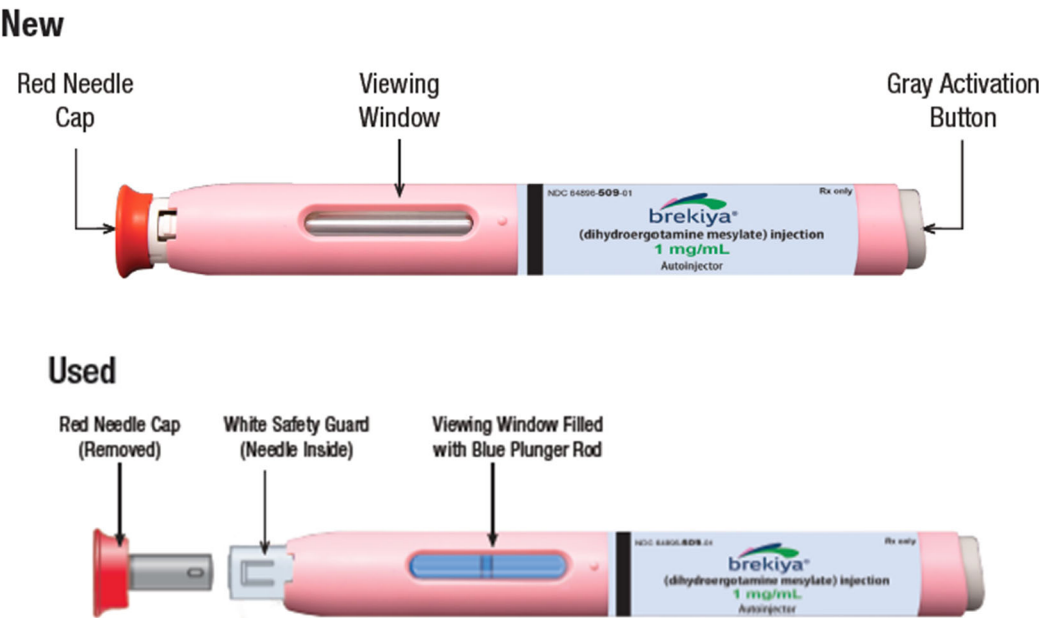


Figure A

Preparing to Inject BREKIYA

Step 1: Wash Hands and Gather Supplies

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1.1 Before you begin, wash your hands with soap and water (See Figure B).



Figure B

1.2 Gather the following supplies (See Figure C):

- BREKIYA autoinjector foil pouch (inside carton)
- Alcohol swab
- Cotton balls or gauze
- Sharps container [See “Throwing Away (Disposing of) BREKIYA”]

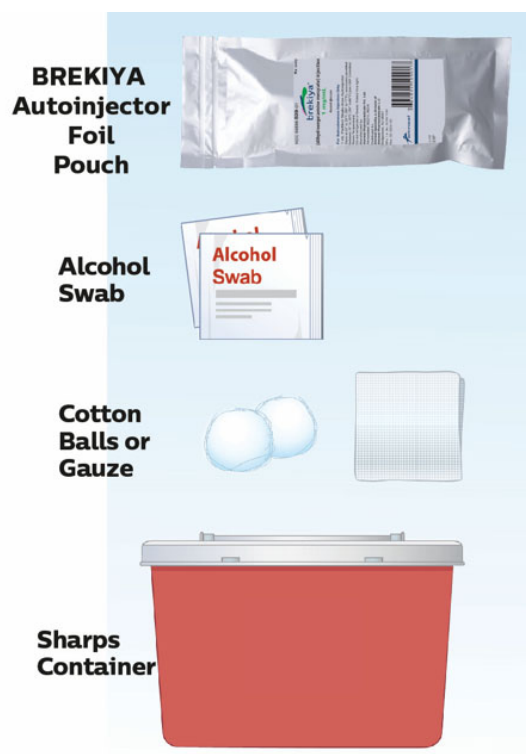


Figure C

Step 2: Remove and Inspect the Autoinjector

2.1 Tear open the foil pouch from the notch to remove the autoinjector (See Figure D).



Figure D

2.2 Check the expiration date printed on the autoinjector (See Figure E). Do not use the autoinjector if the expiration date has passed.

2.3 Check the liquid medicine in BREKIYA by looking through the viewing window (See Figure E). The liquid medicine in BREKIYA should be clear and colorless. It is normal to see one or more air bubbles.

Do not inject if the liquid medicine appears cloudy, discolored, or has floating flakes or particles.

Do not inject if the autoinjector appears to be damaged or broken.

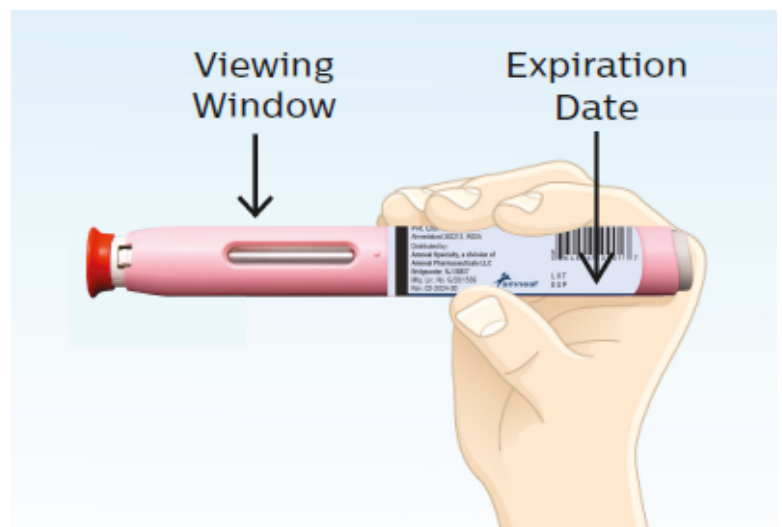


Figure E

Step 3: Select and Prepare Injection Site

3.1 Locate your injection site. BREKIYA autoinjector should be injected into the skin in the middle of your thigh (See Figure F).

Do not inject into moles, scars, birthmarks, or areas where the skin is tender, bruised, red, or hard.

Do not inject through clothing.

Do not inject into the same spot 2 times in a row.

Important: This injection should be at least 2 inches away from the last injection site.



Figure F

3.2 Clean the injection site with an alcohol swab (See Figure G).

Wait for the injection site to air dry before giving the injection. Do not touch the clean injection site again before you inject BREKIYA.



Figure G

Injecting BREKIYA

Step 4: Remove Red Needle Cap and Position the Autoinjector

4.1 Remove the red needle cap by pulling it straight off (See Figure H) and throw it away in the household trash.

Do not bend or twist the cap while removing.

Do not touch the white safety guard after the red needle cap is removed.

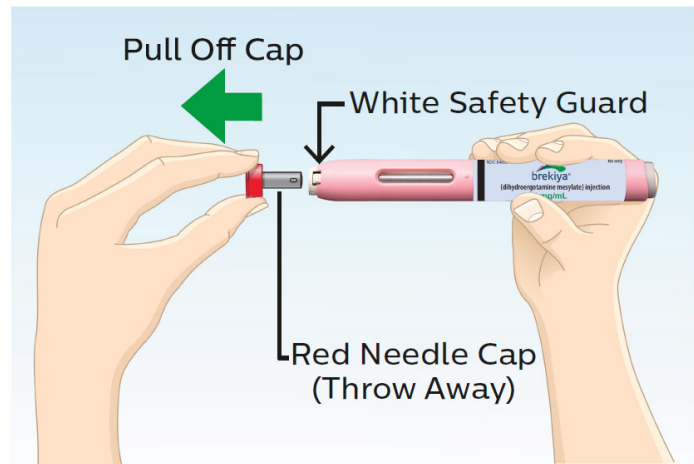


Figure H

4.2 Position the autoinjector straight onto the cleaned injection site with the white safety guard resting on the skin (See Figure I).

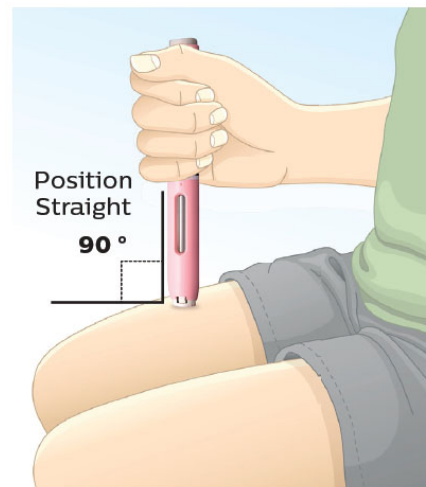


Figure I

Step 5: Give Injection

5.1 Push the autoinjector down against the skin until you do not see the white safety guard (See Figure J).

Important: Keep downward pressure on the skin throughout the injection process.

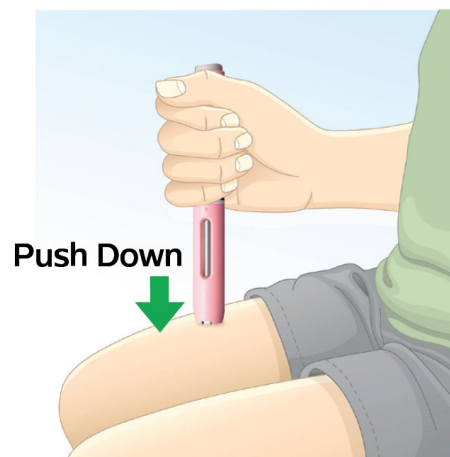


Figure J

5.2 Press and release the gray activation button to start the injection (See Figure K). You will hear a “click” sound when the injection starts.

Be Patient. Do not lift the autoinjector after the first click.

Important: If you do not hear a “click” when you press the gray activation button, make sure that the autoinjector is pressed down against the skin, then try again.

Press and Release Button

1st Click

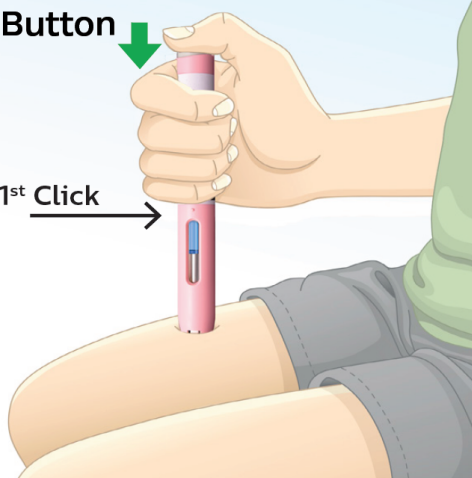


Figure K

5.3 Hold the autoinjector down against the skin for at least 10 seconds to make sure you get the full dose of BREKIYA (See Figure L).

Note: You may hear a second “click”, which means you are close to the end of the injection. Whether or not you hear a second “click” you must hold down the autoinjector against your skin for at least 10 seconds.

Do not lift up the autoinjector early.

Keep Holding Down

2nd Click



Figure L

5.4 Make sure the injection is finished by looking at the viewing window. The viewing window will turn completely blue (See Figure M) when the full dose of BREKIYA has been given.

Note: Even if the inspection window is not completely blue, do not try to use the autoinjector again.

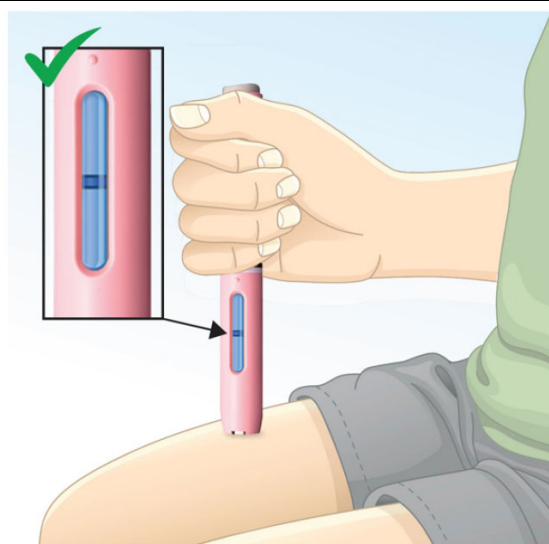


Figure M

Throwing Away (Disposing of) BREKIYA Autoinjector

Step 6: Lift and Throw away (dispose of)

6.1 Lift the autoinjector straight up, away from the skin. The white safety guard will drop down and lock over the needle (See Figure N).

Note: If you think that you have not received the full dose, do not repeat the injection using a new autoinjector. Call your healthcare provider right away for assistance.

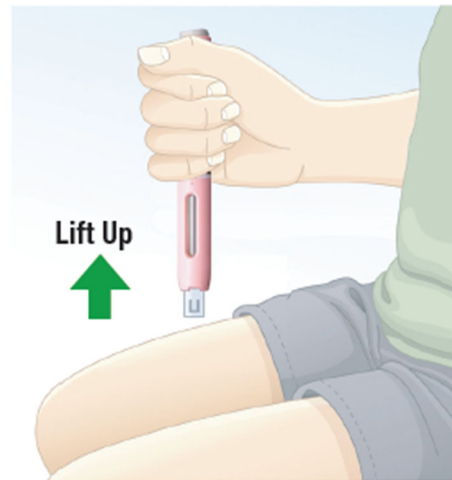


Figure N

6.2 Throw away (dispose of) the used autoinjector into a FDA-cleared sharps disposal container (See Figure O).

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

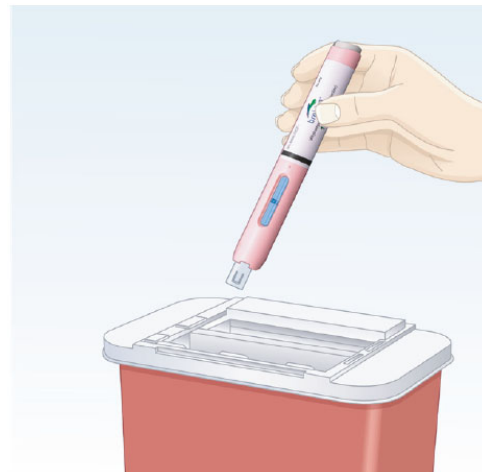


Figure O

6.3 Treat the injection site as needed (See Figure P). It is normal to see a drop of blood or medicine at the injection site. It will not affect your dose.



Figure P

Additional Information on how to Throw Away (Dispose of) BREKIYA

- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and syringes in your household trash.**
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a 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.

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