

INSTRUCTIONS FOR USE
STEQEYMA (ste-qey-ma)
(ustekinumab-stba)
injection, for subcutaneous use

This Instructions for Use contains information on how to inject STEQEYMA using a vial.

Read this Instructions for Use before you start using STEQEYMA. A healthcare provider should show you how to prepare, measure the dose, and give an injection of STEQEYMA the right way.

If you cannot give the injection:

- ask your healthcare provider to help you, or
- ask someone who has been trained by a healthcare provider to give the injections.

Do not try to inject STEQEYMA until you have been shown how to inject STEQEYMA by a healthcare provider.

The STEQEYMA vial is for single-use only (**see Figure A**). It contains 45 mg of STEQEYMA for injection under the skin (subcutaneous injection).



Figure A

Important Information You Need to Know Before Injecting STEQEYMA:

- Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by the healthcare provider.
 - If the dose is 45 mg or less you will receive one 45 mg vial.
 - If the dose is 90 mg, you will receive two 45 mg vials, and **you will need to give two injections, one right after the other.**
- Check the expiration date on the vial and carton. If the expiration date has passed, do not use it. If the expiration date has passed, call the healthcare provider or pharmacist, or call 1-888-804-3433 for help.
- Check the vial for any particles or discoloration. The liquid in the vial should look clear to very slightly opalescent and colorless to pale yellow.
- Do not use STEQEYMA if it is frozen, discolored, cloudy or has particles. Get a new vial.
- **Do not shake the vial at any time.** Shaking the vial may damage the STEQEYMA medicine. If your vial has been shaken, do not use it. Get a new vial.
- Do not use a STEQEYMA vial more than one time, even if there is medicine left in the vial. After the rubber stopper is punctured, STEQEYMA can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused STEQEYMA after you give the injection.
- Safely throw away (dispose of) STEQEYMA vials, needles, and syringes after use. See **“Step 20: Throw away (dispose of) STEQEYMA.”**
- Do not re-use syringes or needles.
- To avoid needle-stick injuries, **do not** recap needles.

Storing STEQEYMA vials

- Store STEQEYMA vials in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store STEQEYMA vials standing up straight (upright).
- Store STEQEYMA vials in the original carton to protect from light until the time of use.
- **Do not** freeze STEQEYMA vial.
- Do not shake STEQEYMA.
- If needed, individual vials may be stored at room temperature up to 86°F (30°C) for a maximum single period of up to 15 days in the original carton to protect from light.
- Record the date when the vial is first removed from the refrigerator on the carton in the space provided.
- After a vial has been stored at room temperature, it should not be returned to the refrigerator.
- Throw away (discard) the vial if not used within 15 days at room temperature storage.

- Do not use STEQEYMA after the expiration date on the carton or on the vial.
Keep STEQEYMA vial and all medicines out of the reach of children.

Preparing to inject STEQEYMA

Step 1. Gather the supplies for the injection.

- Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- Take the carton containing the STEQEYMA vial needed to administer your prescribed dose out of the refrigerator.
- Make sure you have the following supplies (see **Figure B**):

- Carton containing the STEQEYMA vial

Not included in the carton:

- Syringe with needle
- 2 Alcohol wipes
- Cotton ball or gauze
- Adhesive bandage
- FDA-cleared sharps disposal container

Note: You will need a prescription from a healthcare provider to get syringes with the needles attached from a pharmacy.

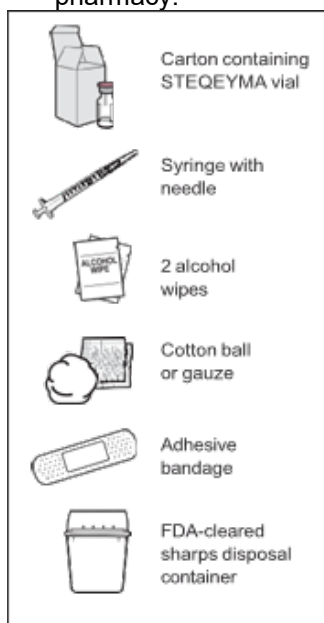


Figure B

Step 2. Check the expiration date on the carton (see Figure C).

- **Do not** use the medicine if the expiration date has passed. If the expiration date has passed, safely throw away (dispose of) the carton in an FDA-cleared sharps disposal container (see **Step 20. Throw away (dispose of) STEQEYMA**).

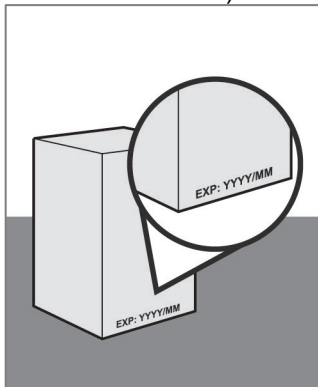


Figure C

Step 3. Wait 30 minutes.

- Leave the carton containing the STEQEYMA vial at room temperature 68°F to 77°F (20°C to 25°C) for 30 minutes to allow it to warm up (see **Figure D**).
- **Do not** warm the vial using heat sources such as hot water or a microwave.
- If the vial does not reach room temperature, this could cause the injection to feel uncomfortable and make it hard to inject.

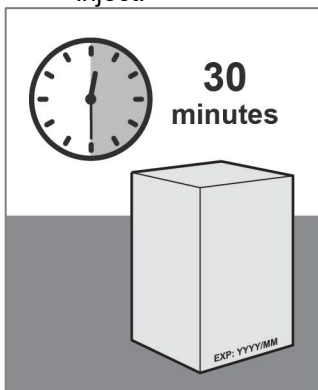


Figure D

Step 4. Wash your hands.

- Wash your hands with soap and water and dry them thoroughly (see **Figure E**).

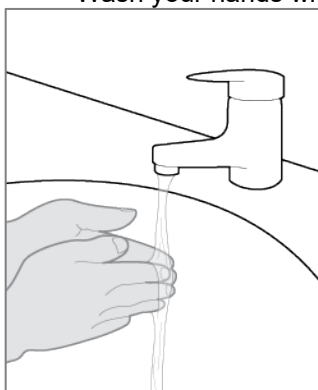


Figure E

Step 5. Inspect the STEQEYMA vial.

- Look at the vial and make sure you have the correct medicine (STEQEYMA) and dosage.
- Look at the vial and make sure it is not cracked or damaged.
- **Do not** use STEQEYMA if the vial has been dropped or damaged.
- Check the expiration date on the label of the vial (see **Figure F**).

- **Do not** use STEQEYMA if the expiration date has passed.

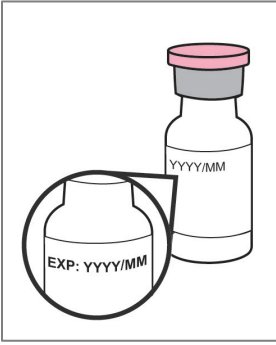


Figure F

Step 6. Inspect the medicine.

- Look at the medicine in the vial to make sure that the liquid is clear to very slightly opalescent and colorless to pale yellow. (see **Figure G**).
- **Do not** use STEQEYMA if the liquid is discolored or cloudy, or if it contains visible flakes or particles.

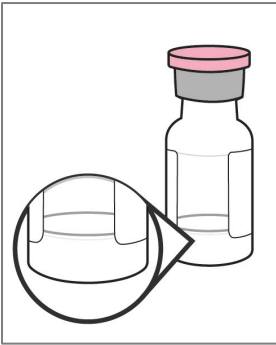


Figure G

Step 7. Choose an injection site (see Figure H).

- Choose an injection site around the stomach area (abdomen), buttocks, and upper legs (thighs). If a caregiver is giving the injection, the outer area of the upper arms may also be used.
- **Use a different injection site for each injection.**
- **Do not** give an injection in an area of the skin that is tender, bruised, red or hard. If possible, do not use areas of skin that show signs of psoriasis.

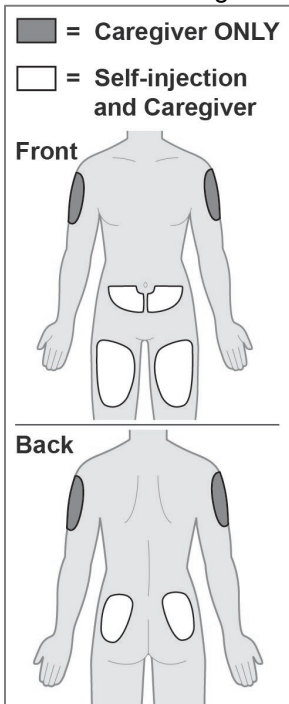


Figure H

Step 8. Clean the injection site.

- Clean the skin with an alcohol wipe where you plan to give the injection (see **Figure I**).
- **Do not** touch this area again before giving the injection. Let the skin dry before injecting.
- **Do not** fan or blow on the clean area.

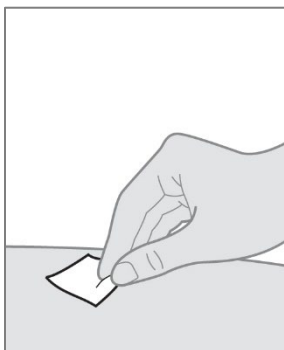


Figure I

Step 9. Remove the protective cap from the vial.

- Remove the protective cap from the STEQEYMA vial. Throw away the cap (see **Figure J**).
- **Do not** remove the rubber stopper.

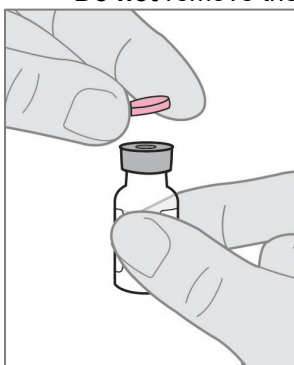


Figure J

Step 10. Clean the rubber stopper.

- Wipe the rubber stopper of the vial with an alcohol wipe and allow it to dry (see **Figure K**).
- **Do not** touch the rubber stopper after you clean it.
- Put the vial on a flat surface.



Figure K

Step 11. Remove the needle cap from the syringe.

- Hold the syringe at the middle of the syringe body with the needle pointing away from yourself, and pull the needle cap straight off the syringe (see **Figure L**).
- Throw away (dispose of) the needle cap right away in an FDA-cleared sharps disposal container (see **Step 20. Throw away (dispose of) STEQEYMA**).
- **Do not** re-cap the syringe.
- **Do not** touch the needle or let the needle touch anything. Doing so may result in a needle stick injury.

- **Do not** use the syringe if it has been dropped without the needle cap in place. Call your healthcare provider for further instructions.

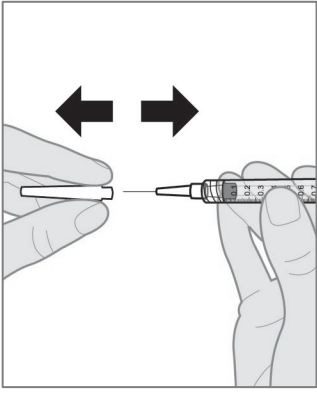


Figure L

Step 12. Draw air into the syringe.

- Pull back on the plunger rod to draw air into the syringe equal to your STEQEYMA dose volume.
- Hold the vial between your thumb and index (pointer) finger.
- Push the needle through the rubber stopper of the vial, and push the plunger rod to inject the air into the vial (see **Figure M**).

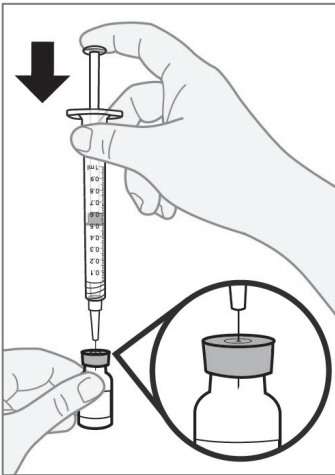


Figure M

Step 13. Withdraw the correct dose.

- Leave the needle in the vial and turn both the syringe and vial upside down (vial on top).
- Hold the syringe and vial firmly in one hand. Make sure the tip of the needle is in the STEQEYMA medicine.
- It is important that the needle tip is always in the medicine. This stops air bubbles from forming in the syringe.
- With your other hand, pull on the plunger rod to fill the syringe with the amount of medicine prescribed by the healthcare provider (see **Figure N**).
- Fill the syringe until the black tip of the plunger lines up with the mark that matches your prescribed dose.

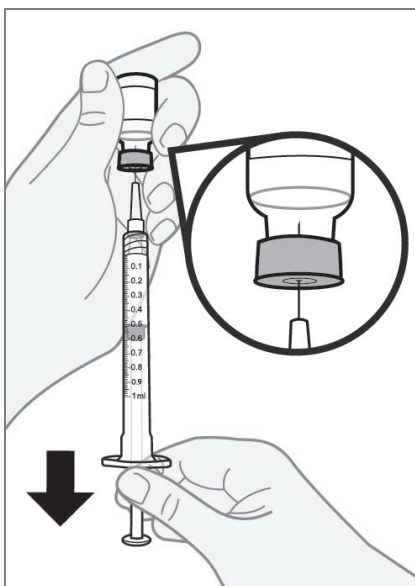


Figure N

Step 14. Check for air bubbles.

- **Do not remove the needle from the vial.** Hold the syringe with the needle pointing up to see if it has any air bubbles inside.
- If there are air bubbles, gently tap the side of the syringe until the air bubbles go to the top of the syringe (see **Figure O**).
- Slowly press the plunger rod until all of the air bubbles (but none of the medicine) have been removed.
- Remove the syringe from the vial. Do not lay the syringe down or allow the needle to touch anything.

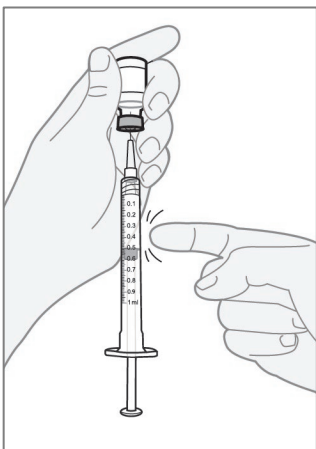


Figure O

Injecting STEQEYMA

Step 15. Insert the needle into the injection site.

- Hold the body of the syringe in one hand between the thumb and index fingers (see **Figure P**).
- **Do not pull back on the plunger rod at any time.**
- Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
Note: Pinching the skin is important to make sure that you inject under the skin (into the fatty area) but not any deeper (into muscle).
- Use a quick and dart-like motion to insert the needle into the pinched skin at about a 45-degree angle (see **Figure P**).

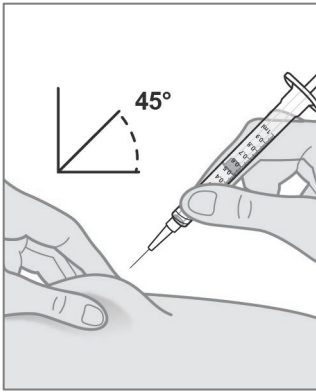


Figure P

Step 16. Give the injection.

- After the needle is inserted use your thumb to slowly and evenly push the plunger rod all the way to the bottom of the syringe body. Keep the skin gently pinched.
- Make sure you have injected all of the STEQEYMA medicine (see **Figure Q**).

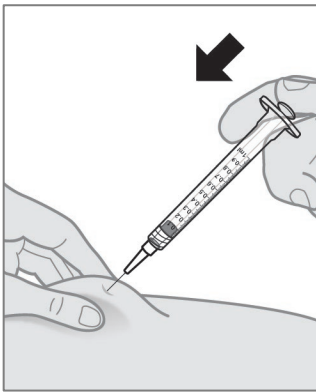


Figure Q

Step 17. Remove the syringe from the injection site.

- After the syringe is empty, release the pinched skin and slowly pull the needle out of the injection site. (see **Figure R**).
- **Do not** re-cap the used needle. Recapping the used needle can lead to a needle-stick injury.
- **Do not** rub the injection site.
- There may be some bleeding at the injection site. This is normal (see **Step 18. Care for the injection site**).

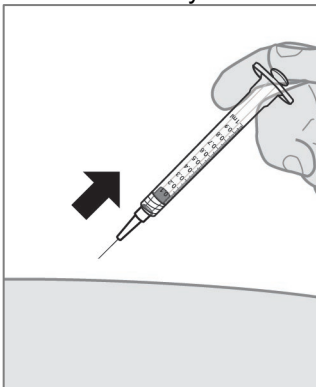


Figure R

After the Injection

Step 18. Care for the injection site.

- **Do not** rub the injection site.
- There may be a small amount of blood or liquid at the injection site. This is normal.

If some bleeding occurs, you can press a cotton ball or gauze over the injection site and hold for 10 seconds. You may cover the injection site with a small adhesive bandage, if necessary.

Step 19. If your dose requires 2 injections, give the second injection right after the first.

- If your dose is 90 mg, you will have two 45 mg vials. You will need to give a second injection right after the other.
- Repeat **Steps 5 to 18** for the second injection using a new vial and syringe with needle.
- Choose a different site for the second injection.

Step 20. Throw away (dispose of) STEQEYMA.

- Put the used needle, syringe and vial in an FDA-cleared sharps disposal container right away after use (see **Figure S**).
- **Do not throw away (dispose of) the syringe in your household trash.**
- Never re-use needles and syringes, for your safety and health, and for the safety of others.
- Alcohol wipes, and other supplies can be disposed of 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 it. 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.



Figure S

If you have any questions about using your STEQEYMA vial, please call your healthcare provider or CELLTRION at 1-888-804-3433.

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

Revised: 12/2025

INSTRUCTIONS FOR USE
STEQEYMA (ste-qey-ma)
(ustekinumab-stba)
injection, for subcutaneous use

This Instructions for Use contains information on how to inject STEQEYMA using a prefilled syringe.

Read this Instructions for Use before you start using STEQEYMA. A healthcare provider should show you how to prepare and give an injection of STEQEYMA the right way.

If you cannot give the injection:

- ask your healthcare provider to help you, or
- ask someone who has been trained by a healthcare provider to give your injections.

Do not try to inject STEQEYMA until you have been shown how to inject STEQEYMA by a healthcare provider.

STEQEYMA prefilled syringes are available in 2 dose strengths (see **Figure A**). These instructions can be used for both dose strengths.

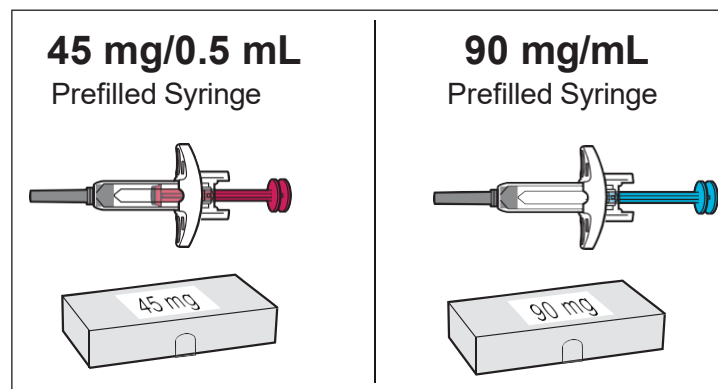


Figure A

Important Information You Need to Know Before Injecting STEQEYMA:

- **For subcutaneous use only** (inject directly under the skin).
- Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by the healthcare provider.
 - If the dose is 45 mg, you will receive one 45 mg prefilled syringe.
 - If the dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes. **If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give two injections, one right after the other.**
- Check the expiration date on the prefilled syringe and carton. If the expiration date has passed or if the prefilled syringe has been kept at room temperature up to 86°F (30°C) for longer than 15 days, do not use it. Call the healthcare provider or pharmacist, or call 1-888-804-3433 for help.
- **Do not** use the prefilled syringe if the liquid is discolored, cloudy, or has particles. Get a new prefilled syringe.
- **Do not shake the prefilled syringe at any time.** Shaking the prefilled syringe may damage the STEQEYMA medicine. If the prefilled syringe has been shaken, **do not** use it. Get a new prefilled syringe.
- To reduce the risk of accidental needle sticks, each prefilled syringe has a needle safety guard that is automatically activated to cover the needle after you have given the injection. **Do not** pull back on the plunger rod at any time.

Storing STEQEYMA prefilled syringes

- Store STEQEYMA prefilled syringes in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Store STEQEYMA prefilled syringes in the original carton to protect from light.
- **Do not** freeze STEQEYMA prefilled syringes.
- Do not shake STEQEYMA.
- If needed, STEQEYMA prefilled syringe may be stored at room temperature up to 86°F (30°C) for a maximum single period of up to 15 days in the original carton to protect from light.
- Record the date when the prefilled syringe is removed from the refrigerator on the carton in the space provided.
- After a prefilled syringe has been stored at room temperature, do not return it to the refrigerator.

- Throw away (discard) the prefilled syringe if it is not used within 15 days at room temperature storage.
 - Do not use STEQEYMA after the expiration date on the carton or the prefilled syringe.
- Keep STEQEYMA and all medicines out of the reach of children.

Parts of the Prefilled Syringe (see Figure B)

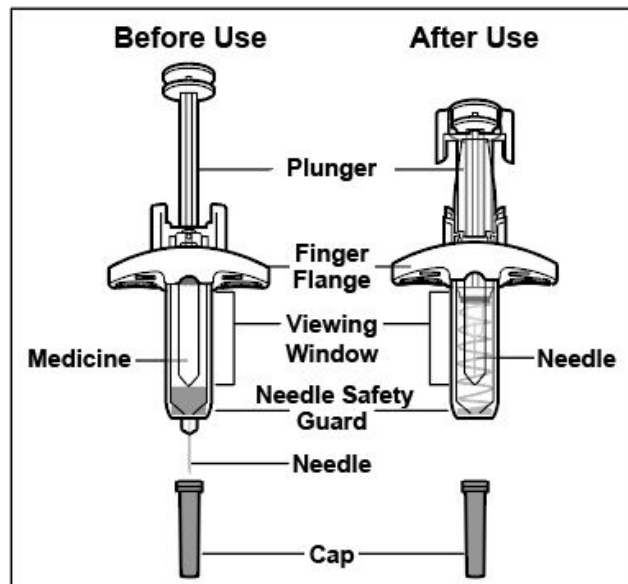


Figure B

Preparing to Inject STEQEYMA

Carton containing prefilled syringe Cotton ball or gauze and alcohol wipe Adhesive bandage Sharps disposal container	Step 1. Gather the supplies for the injection • Prepare a clean, flat surface, such as a table or counter top, in a well-lit area. • Take the carton(s) containing the prefilled syringe(s) needed to administer your prescribed dose out of the refrigerator. Each STEQEYMA carton contains 1 prefilled syringe. Note: Depending on the dose prescribed to you by your healthcare provider you may need to prepare 1 or more prefilled syringes and inject the contents of them all. • Make sure you have the following supplies (see Figure C) ○ Carton containing prefilled syringe Not included in the carton: ○ Cotton ball or gauze ○ Adhesive bandage ○ FDA-cleared sharps disposal container ○ Alcohol wipe
	Step 2. Check the expiration date on the carton (see Figure D). • Do not use it if the expiration date has passed. If the expiration date has passed, safely throw away (dispose of) the carton in an FDA-cleared sharps disposal container (see Step 13. Throw away (dispose of) STEQEYMA).

Figure D

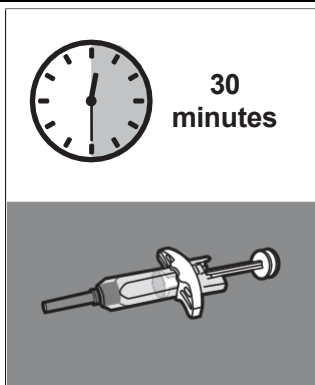


Figure E

Step 3. Wait 30 minutes.

- Open the carton. Gripping from the syringe body, lift the prefilled syringe from the carton.
- Leave the prefilled syringe outside of the carton at room temperature 68°F to 77°F (20°C to 25°C) for 30 minutes to allow it to warm up (see **Figure E**).
- **Do not** warm the prefilled syringe using heat sources such as hot water or a microwave.
- If the prefilled syringe does not reach room temperature, this could cause the injection to feel uncomfortable and make it hard to push the plunger.



Figure F

Step 4. Wash your hands.

- Wash your hands with soap and water and dry them thoroughly (see **Figure F**).

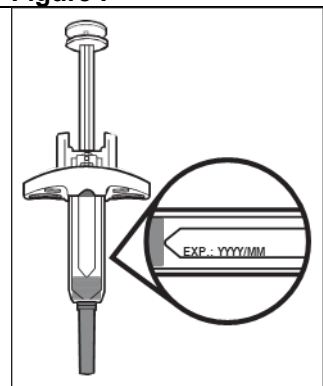


Figure G

Step 5. Inspect the prefilled syringe.

- Look at the prefilled syringe and make sure you have the correct medicine (STEQEYMA) and dosage.
- Look at the prefilled syringe and make sure it is not cracked or damaged.
- Check the expiration date on the label of the prefilled syringe (see **Figure G**).
- **Do not** use if the expiration date has passed.

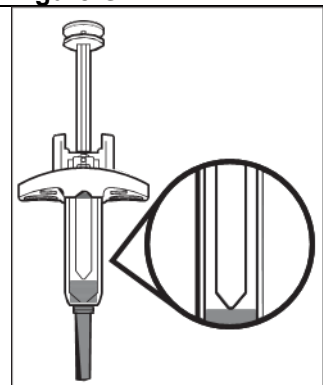


Figure H

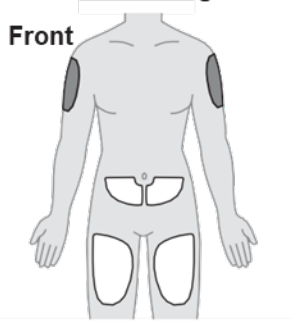
Step 6. Inspect the medicine.

- Look at the medicine and make sure that the liquid is clear to very slightly opalescent and colorless to pale yellow. (see **Figure H**).
- **Do not** use the prefilled syringe if the liquid is discolored, cloudy, or has particles. Get a new prefilled syringe.
- You may see air bubbles in the liquid. This is normal.

■ = Caregiver ONLY

□ = Self-injection
and Caregiver

Front



Back

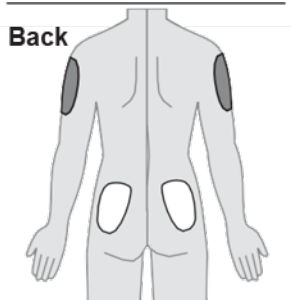


Figure I

Step 7. Choose an injection site (see Figure I).

- Choose an injection site around the stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving the injection, the outer area of the upper arms may also be used (see **Figure I**).
- **Use a different injection site for each injection.**
- **Do not** give an injection in an area of the skin that is tender, bruised, red or hard.

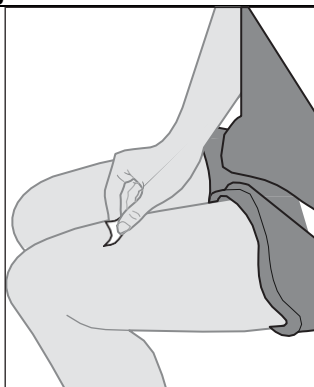


Figure J

Step 8. Clean the injection site.

- Clean the skin with an alcohol wipe where you plan to give the injection (see **Figure J**).
- **Do not** touch this area again before giving the injection. Let the skin dry before injecting.
- **Do not** fan or blow on the clean area.

Injecting STEQEYMA

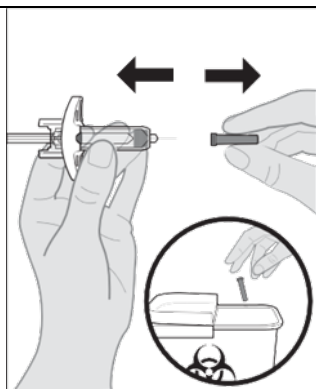


Figure K

Step 9. Remove the cap.

- Remove the needle cap when you are ready to inject STEQEYMA by holding the body of the prefilled syringe in one hand between the thumb and index fingers (see **Figure K**).
- **Do not** hold the plunger while removing the cap.
- You may see a few drops of liquid at the tip of the needle. This is normal.
- Throw away (dispose of) the cap right away in an FDA-cleared sharps disposal container (see **Step 13. Throw away (dispose of) STEQEYMA**).
- **Do not** re-cap the prefilled syringe.
- **Do not** touch the needle. Doing so may result in a needle stick injury.
- **Do not** use the prefilled syringe if it has been dropped without the needle cover in place.

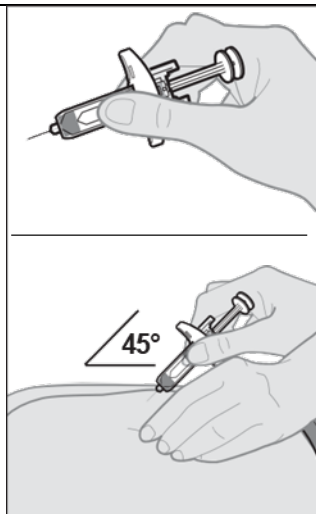


Figure L

Step 10. Insert the prefilled syringe into the injection site.

- Hold the body of the prefilled syringe in one hand between the thumb and index fingers (see **Figure L**).
- **Do not pull back on the plunger rod at any time.**
- Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
Note: Pinching the skin is important to make sure that you inject under the skin (into the fatty area) but not any deeper (into muscle).
- Use a quick and dart-like motion to insert the needle into the pinched skin at about a 45-degree angle (see **Figure L**).

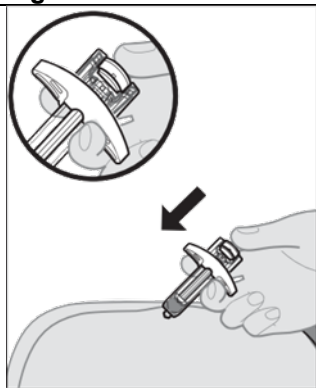


Figure M

Step 11. Give the injection.

- After the needle is inserted, release the pinch.
- Inject all of the liquid by using your thumb to push the plunger all the way down (see **Figure M**).
- If the plunger is not fully pressed, the needle safety guard will not extend to cover the needle when it is removed.

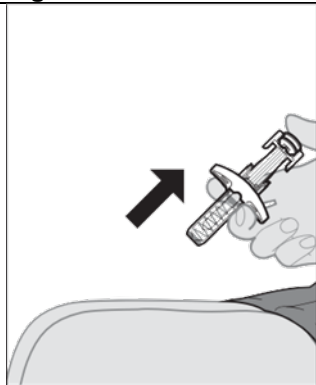


Figure N

Step 12. Remove the prefilled syringe from the injection site.

- After the prefilled syringe is empty, slowly lift your thumb from the plunger rod until the needle is completely covered by the needle safety guard (see **Figure N**).
- If the needle is not covered, proceed carefully to throw away (dispose of) the syringe (see **Step 13. Throw away (dispose of) STEQEYMA**).
- Some bleeding may occur. This is normal (see **Step 14. Care for the injection site**).
- **Do not** rub the injection site.

If the dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes. If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give a second injection right after the first.

Repeat Steps 1 to 12 for the second injection using a new syringe. Choose a different site for the second injection.

After the Injection



Figure O

Step 13. Throw away (dispose of) STEQEYMA.

- Put the used prefilled syringe in an FDA-cleared sharps disposal container right away after use (see **Figure O**).
- STEQEYMA prefilled syringe is a single-dose syringe and should not be used again.
- **Do not throw away (dispose of) the prefilled syringe 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 it. 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.

Step 14. Care for the injection site.

- If some bleeding occurs, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.

If you have any questions about using your STEQEYMA prefilled syringe, please call your healthcare provider or CELLTRION at 1-888-804-3433.

Manufactured by: CELLTRION, Inc. 23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea, US License No. 1996

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