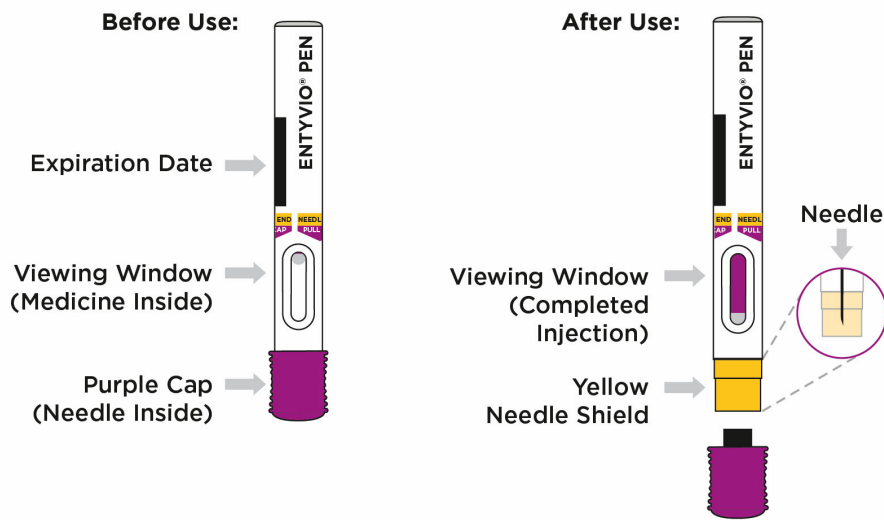


INSTRUCTIONS FOR USE
ENTYVIO® (en ti' vee oh) PEN
(vedolizumab)
injection, for subcutaneous use
 Single-dose prefilled pen

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

Your ENTYVIO single-dose prefilled pen



Important information you need to know before injecting ENTYVIO:

- Read and follow this Instructions for Use before you inject ENTYVIO.
- Your healthcare provider should show you how to use the ENTYVIO PEN before you use it for the first time.
- **ENTYVIO PEN is for subcutaneous injection only** (inject directly into fatty layer under the skin).
- **Do not** shake the prefilled pen.
- **Do not remove the purple cap from the prefilled pen until you are ready to inject.**
- **Do not** put or press your thumb, fingers, or hand over the yellow needle shield. The yellow needle shield is visible when the purple cap is removed.
- **Do not** use the prefilled pen if it is dropped or damaged.

Storing ENTYVIO

- Store your prefilled pen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Your prefilled pen can be left in its box at room temperature up to 77°F (25°C) for up to 7 days (for example, when traveling). **Do not** use the prefilled pen if it is left out of the refrigerator for more than 7 days.
- **Do not** freeze the prefilled pen.
- **Do not** leave the prefilled pen in direct sunlight.

- Throw away the prefilled pen in a FDA-cleared sharps disposal container if it has been left out of the refrigerator for more than 7 days, frozen, or left in direct sunlight. See **Step 14** for instructions on how to throw away (dispose of) the prefilled pen.
- **Always keep ENTYVIO PENS, the sharps disposal container, and all medicines out of the reach of children.**

Getting Your Supplies Ready

Step 1. Remove the ENTYVIO PEN box from the refrigerator

Take 1 prefilled pen box from the refrigerator and check the expiration date on the box (see **Figure A**).

- **Do not** use the prefilled pen if any of the seals on the box are broken.
- **Do not** use the prefilled pen if the expiration date on the box has passed.

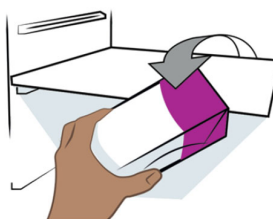


Figure A

Step 2. Wait 30 minutes

Wait 30 minutes and let the prefilled pen come to room temperature (see **Figure B**).

- **Do not** warm the prefilled pen any other way.
- **Do not** let the prefilled pen sit in direct sunlight.
- **Do not** take the prefilled pen out of its tray until you are ready to inject.

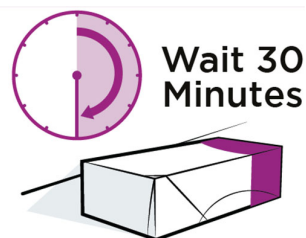


Figure B

Step 3. Gather supplies

Find a clean, flat surface like a table. Gather supplies that are not in the prefilled pen box (see **Figure C**).

- Alcohol pad
- Cotton ball or gauze
- Sharps disposal container (see **Step 14** "Throw away (dispose of) the prefilled pen")

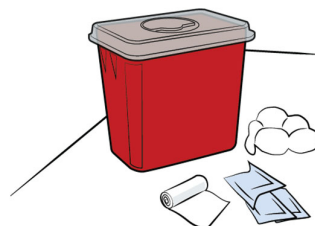


Figure C

Preparing to Inject ENTYVIO

Step 4. Wash hands

Wash your hands with soap and clean water (see **Figure D**).



Figure D

Step 5. Remove the prefilled pen from the tray

Peel off the paper on the tray and lift the prefilled pen straight out (see **Figure E**).

- **Do not** shake the prefilled pen.
- **Do not** remove the purple cap from the prefilled pen until **Step 9**.

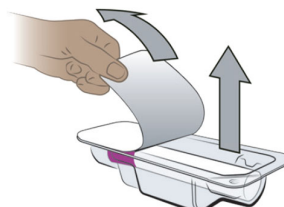


Figure E

Step 6. Inspect the prefilled pen

Check the expiration date (EXP) printed on the prefilled pen and the medicine in the prefilled pen viewing window (see **Figure F**). The medicine should be colorless to pale yellow. It is normal to see air bubbles. Inspect the prefilled pen for any damage.

- **Do not** use the prefilled pen if the expiration date on the prefilled pen has passed.
- **Do not** use the prefilled pen if the medicine is cloudy or has particles floating in it.
- **Do not** use the prefilled pen if any part of it is damaged.

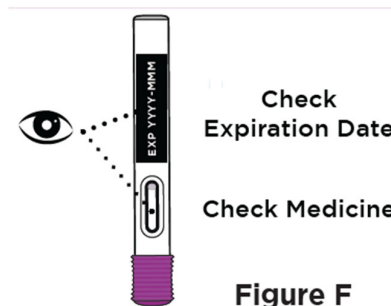


Figure F

Step 7. Choose injection site

Choose an injection site on your bare skin from one of the following (see **Figure G**):

- front of the thighs
- stomach area (avoid the area 2 inches around the belly button)

For caregivers only: back of the upper arms may also be used.

- **Do not** inject into the same spot you used for your last injection.
- **Do not** inject into moles, scars, bruises, or skin that is tender, hard, red, or damaged.

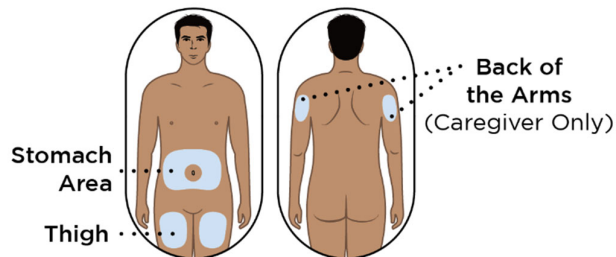


Figure G

Step 8. Clean the injection site

Clean the injection site with an alcohol pad (see **Figure H**). Let your skin dry.

- **Do not** touch or blow on the cleaned injection site before you inject.

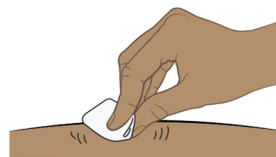


Figure H

Continue to **Step 9** →

Injecting ENTYVIO

Step 9. Remove the purple cap and throw it away

When you are ready to inject, pull the purple cap straight off and throw it right away in the sharps disposal container (see **Figure I**).

- The needle is inside the yellow needle shield (under purple cap).
- **Do not** put or press your thumb, fingers, or hand over the yellow needle shield.
- **Do not** put the purple cap back on. This could accidentally start the injection.

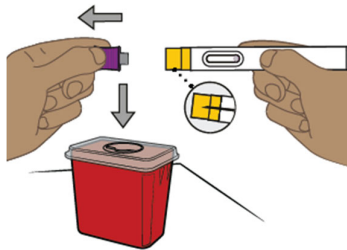


Figure I

Step 10. Place the prefilled pen on the injection site

- Hold the prefilled pen so you can see the viewing window.
- Place the yellow end of the prefilled pen flat on your skin at 90 degrees to the injection site (see **Figure J**).
- The needle is inside the yellow needle shield.
- **Do not** push down on the prefilled pen until you are ready to inject.

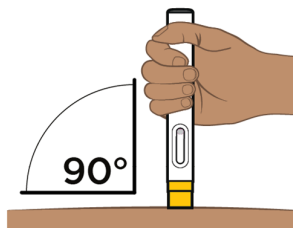


Figure J

Step 11. Start injecting ENTYVIO

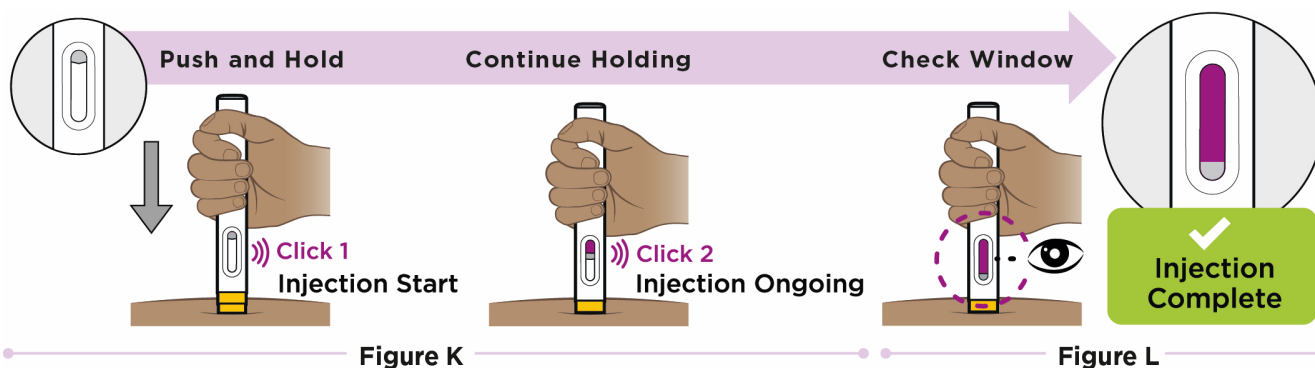
Push the prefilled pen straight down and hold for at least 10 seconds (see **Figure K**).

- You may hear a first click when the injection starts.
- You may hear a second click. This is not the end of the injection.
- **Continue holding the prefilled pen** with constant pressure and watch the window turn purple.

Step 12. Complete injecting ENTYVIO

Continue holding the prefilled pen with constant pressure until **the viewing window has filled with purple to make sure you have received your full dose** (see **Figure L**).

- You will see a small amount of gray in the viewing window. This is normal.
- If the viewing window did not fill with purple, you may not have received your full dose. Call your pharmacy or healthcare provider.



Step 13. Lift prefilled pen from skin

Lift the prefilled pen from the injection site (see **Figure M**). The yellow needle shield will drop down and lock over the needle.

- When you remove the prefilled pen, if the window has not turned purple, or it looks like the medicine is still coming out of the prefilled pen, this means you have not received a full dose. Call your pharmacy or healthcare provider right away.
- You may see a small amount of blood at the injection site. If you do, press on your skin with a cotton ball or gauze.

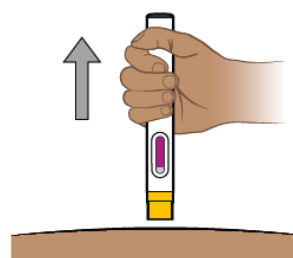


Figure M

Step 14. Throw away (dispose of) the prefilled pen

Throw away (dispose of) the used prefilled pen in a FDA-cleared sharps disposal container right away after use (see **Figure N**). **Do not** recycle or throw away the prefilled pen in your household trash.

- Throw away the remaining supplies in your household trash or sharps disposal container.
- 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 local or state laws about how you should throw away needles and syringes.
- For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at:
<http://www.fda.gov/safesharpsdisposal>.

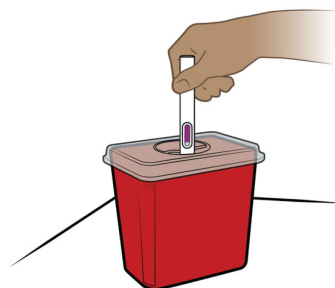


Figure N

If you have questions or concerns about your ENTYVIO PEN, please call your healthcare provider. You can also call 877-825-3327 or visit www.ENTYVIO.com for more information.

Manufactured by:
Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421

U.S. License No. 1898

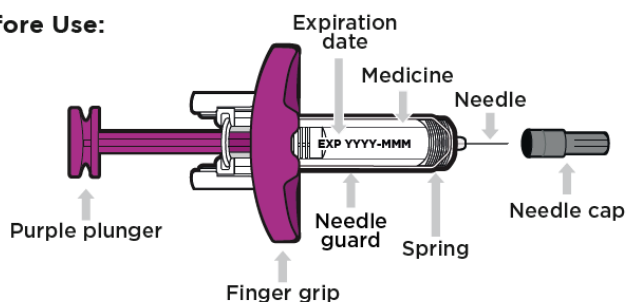
This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Approved: 9/2023

INSTRUCTIONS FOR USE
ENTYVIO® (en ti' vee oh)
(vedolizumab)
injection, for subcutaneous use
 Single-dose prefilled syringe

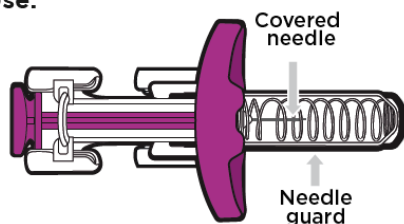
This Instructions for Use contains information on how to inject ENTYVIO.

Your ENTYVIO single-dose prefilled syringe

Before Use:



After Use:



Important information you need to know before injecting ENTYVIO:

- Read and follow this Instructions for Use before you inject ENTYVIO.
- Your healthcare provider should show you how to use the ENTYVIO prefilled syringe before you use it for the first time.
- **ENTYVIO prefilled syringe is for subcutaneous injection only** (inject directly into fatty layer under the skin).
- **Do not** shake the prefilled syringe.
- **Do not remove the needle cap from the prefilled syringe until you are ready to inject.**
- **Do not** use the prefilled syringe if it is dropped or damaged.
- Each prefilled syringe has a needle guard. It will automatically cover the needle after the injection is completed to reduce the risk of accidental needle sticks.

Storing ENTYVIO

- Store your prefilled syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).

- Your prefilled syringe can be left in its box at room temperature up to 77°F (25°C) for up to 7 days (for example, when traveling). **Do not** use the prefilled syringe if it is left out of the refrigerator for more than 7 days.
- **Do not** freeze the prefilled syringe.
- **Do not** leave the prefilled syringe in direct sunlight.
- Throw away the prefilled syringe in a FDA-cleared sharps disposal container if it has been left out of the refrigerator for more than 7 days, frozen, or left in direct sunlight. See **Step 14** for instructions on how to throw away (dispose of) the prefilled syringe.
- **Always keep ENTYVIO prefilled syringes, the sharps disposal container, and all medicines out of the reach of children.**

Getting Your Supplies Ready

Step 1. Remove the ENTYVIO prefilled syringe box from the refrigerator

Take 1 prefilled syringe box from the refrigerator and check the expiration date on the box (see **Figure A**).

- **Do not** use the prefilled syringe if any of the seals on the box are broken.
- **Do not** use the prefilled syringe if the expiration date on the box has passed.

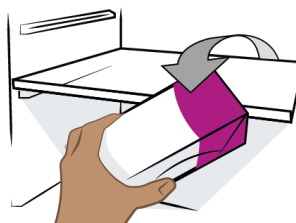


Figure A

Step 2. Wait 30 minutes

Wait 30 minutes and let the prefilled syringe come to room temperature (see **Figure B**).

- **Do not** warm the prefilled syringe any other way.
- **Do not** let the prefilled syringe sit in direct sunlight.
- **Do not** take the prefilled syringe out of its tray until you are ready to inject.

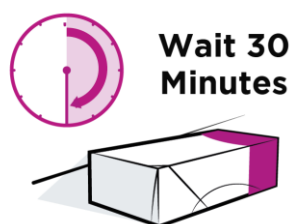


Figure B

Step 3. Gather supplies

Find a clean, flat surface like a table. Gather supplies that are not in the prefilled syringe box (see **Figure C**).

- Alcohol pad
- Cotton ball or gauze
- Sharps disposal container (see **Step 14** “Throw away (dispose of) the prefilled syringe”)

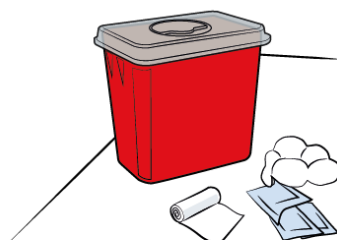


Figure C

Preparing to Inject ENTYVIO

Step 4. Wash hands

Wash your hands with soap and clean water (see **Figure D**).



Figure D

Step 5. Remove the prefilled syringe from the tray

Peel off the paper on the tray and lift the prefilled syringe straight out (see **Figure E**).

- **Do not** lift from the purple plunger.
- **Do not** shake the prefilled syringe.
- **Do not** remove the needle cap from the prefilled syringe until **Step 9**.

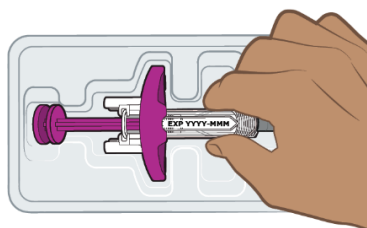


Figure E

Step 6. Inspect the prefilled syringe

Check the expiration date (EXP) printed on the prefilled syringe and the medicine in the prefilled syringe (see **Figure F**). The medicine should be colorless to pale yellow. It is normal to see air bubbles. Inspect the prefilled syringe for any damage.

- **Do not** use the prefilled syringe if the expiration date on the prefilled syringe has passed.
- **Do not** use the prefilled syringe if the medicine is cloudy or has particles floating in it.
- **Do not** use the prefilled syringe if any part of it is damaged.
- **Do not** try to remove air bubbles from the prefilled syringe.

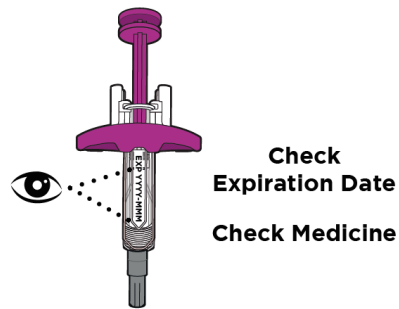


Figure F

Step 7. Choose injection site

Choose an injection site on your bare skin from one of the following (see **Figure G**):

- front of the thighs
- stomach area (avoid the area 2 inches around the belly button)

For caregivers only: back of the upper arms may also be used.

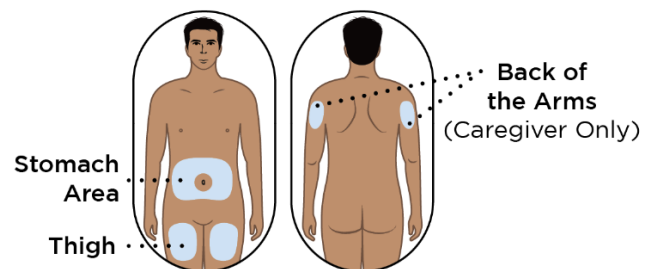


Figure G

- **Do not** inject into the same spot you used for your last injection.
- **Do not** inject into moles, scars, bruises, or skin that is tender, hard, red, or damaged.

Step 8. Clean the injection site

Clean the injection site with an alcohol pad (see **Figure H**). Let your skin dry.

- **Do not** touch or blow on the cleaned injection site before you inject.

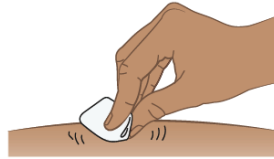


Figure H

Continue to **Step 9** →

Injecting ENTYVIO

Step 9. Remove the needle cap and throw it away

When you are ready to inject, pull the needle cap straight off and throw it right away in the sharps disposal container (see **Figure I**). You may see a drop of liquid at the end of the needle. This is normal.

- **Do not** touch or pull back the purple plunger.
- **Do not** touch or re-cap the needle.
- **Do not** use a prefilled syringe with a bent or broken needle.

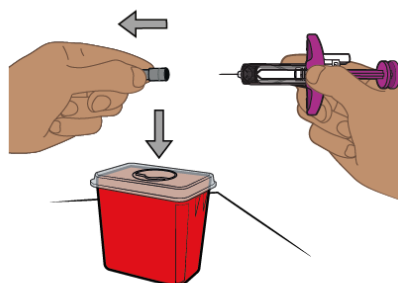


Figure I

Step 10. Pinch the skin

With the needle cap off, hold the prefilled syringe with one hand and pinch the skin around the injection site with your other hand (see **Figure J**).

- Hold the pinch until the injection is completed.

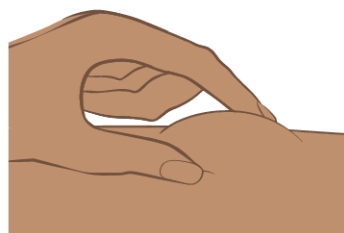


Figure J

Step 11. Insert the prefilled syringe at 45-degree angle

Insert the needle at about a 45-degree angle all the way into the pinched skin (see **Figure K**).

- Avoid touching the plunger until the needle is inserted.

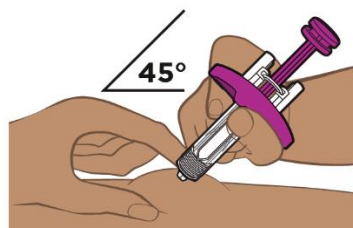
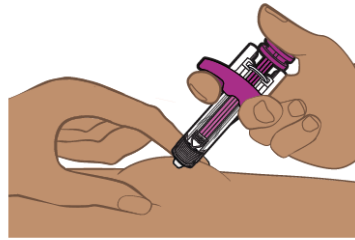


Figure K

Step 12. Push down on the plunger

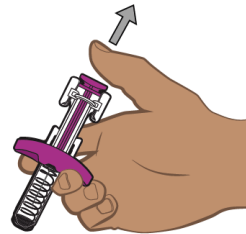
Push the plunger all the way down until all the medicine is injected (see **Figure L**).

- **Keep pressure on the plunger** and take the needle out of the skin.
- If you are not able to start or cannot complete the injection by pushing the plunger all the way down, you may not have received your full dose. Call your pharmacy or healthcare provider.

**Figure L****Step 13. Take your thumb off the plunger**

Take your thumb off the plunger to allow the needle guard to cover the needle (see **Figure M**).

- You may see a small amount of blood at the injection site. If you do, press on your skin with a cotton ball or gauze.

**Figure M**

Step 14. Throw away (dispose of) the prefilled syringe

Throw away (dispose of) the used prefilled syringe in a FDA-cleared sharps disposal container right away after use (see **Figure N**). **Do not** recycle or throw away the prefilled syringe in your household trash.

- Throw away the remaining supplies in your household trash or sharps disposal container.
- 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 local or state laws about how you should throw away needles and syringes.
- For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at:
<http://www.fda.gov/safesharpsdisposal>.

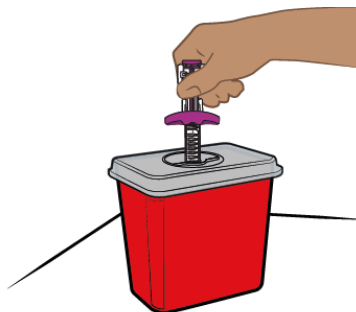


Figure N

If you have questions or concerns about your ENTYVIO prefilled syringe, please call your healthcare provider. You can also call 877-825-3327 or visit www.ENTYVIO.com for more information.

Manufactured by:
Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421

U.S. License No. 1898

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Approved: 9/2023