

MEDICATION GUIDE		
ENTYVIO® (en ti' vee oh) (vedolizumab) for injection, for intravenous use	ENTYVIO® (en ti' vee oh) (vedolizumab) injection, for subcutaneous use	ENTYVIO® (en ti' vee oh) PEN (vedolizumab) injection, for subcutaneous use
<p>What is the most important information I should know about ENTYVIO? ENTYVIO may cause serious side effects, including:</p> <ul style="list-style-type: none"> • Infusion-related and serious allergic reactions. These reactions can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing). • Infections. ENTYVIO may increase your risk of getting a serious infection. Before receiving ENTYVIO and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or have symptoms of an infection such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination. If your healthcare provider feels that you are at risk for tuberculosis (TB), you may be treated with medicine for TB before you begin treatment with ENTYVIO. • Progressive Multifocal Leukoencephalopathy (PML). People with weakened immune systems can get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). Although unlikely while receiving ENTYVIO, a risk of PML cannot be ruled out. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. Tell your healthcare provider right away if you have any of the following symptoms: confusion or problems thinking, loss of balance, change in the way you walk or talk, decreased strength or weakness on one side of the body, blurred vision, or loss of vision. • Liver Problems. Liver problems can happen in people who receive ENTYVIO. Tell your healthcare provider right away if you have any of the following symptoms: tiredness, loss of appetite, pain on the right side of your stomach (abdomen), dark urine, or yellowing of the skin and eyes (jaundice). <p>See “What are the possible side effects of ENTYVIO?” for more information about side effects.</p>		
<p>What is ENTYVIO? ENTYVIO is a prescription medicine used in adults for the treatment of:</p> <ul style="list-style-type: none"> • moderately to severely active ulcerative colitis (UC). • moderately to severely active Crohn’s disease (CD). <p>It is not known if ENTYVIO is safe and effective in children under 18 years of age.</p>		
<p>Who should not receive ENTYVIO? Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of the ingredients in ENTYVIO. See the end of this Medication Guide for a complete list of ingredients in ENTYVIO.</p>		
<p>Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> • have an infection, think you may have an infection or have infections that keep coming back (see “What is the most important information I should know about ENTYVIO?”). • have liver problems. • have TB or have been in close contact with someone with TB. • have recently received or are scheduled to receive a vaccine. Talk to your healthcare provider about bringing your vaccines up-to-date before starting treatment with ENTYVIO. • are pregnant or plan to become pregnant. It is not known if ENTYVIO will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ENTYVIO. • are breastfeeding or plan to breastfeed. ENTYVIO can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ENTYVIO. <p>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.</p> <p>Especially tell your healthcare provider if you take or have recently taken Tysabri (natalizumab), Tyruko (natalizumab-sztn), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.</p>		

How should I use ENTYVIO?**When given in a vein (intravenously):**

- You may receive ENTYVIO through a needle placed in a vein (intravenous infusion) in your arm.
 - ENTYVIO is given to you over a period of about 30 minutes.
 - Your healthcare provider will monitor you during and after the ENTYVIO infusion for side effects to see if you have a reaction to the treatment.

When given under the skin (subcutaneously):

- You may receive ENTYVIO as an injection under your skin (subcutaneous) every 2 weeks. You may receive your first subcutaneous injection after at least 2 intravenous infusions in place of the next scheduled intravenous infusion.
 - **See the detailed Instructions for Use that comes with ENTYVIO about the right way to prepare and give ENTYVIO.**
 - ENTYVIO is provided as single-dose prefilled syringe or single-dose prefilled pen (ENTYVIO PEN) for subcutaneous use. Your healthcare provider will prescribe the type that is best for you.
 - If your healthcare provider decides that you or your caregiver can give your injections of ENTYVIO at home, you or your caregiver should be shown the right way to prepare and inject ENTYVIO.
 - Do not inject ENTYVIO until you or your caregiver have been shown the right way by your healthcare provider.
 - Always check the label of your prefilled syringe or prefilled pen to make sure you have the correct medicine before each injection.
 - Do not shake ENTYVIO.
 - ENTYVIO is injected under your skin (subcutaneously) 1 time every 2 weeks.
 - Inject ENTYVIO under the skin (subcutaneous injection) in your upper legs (thighs) or stomach area (abdomen). The upper arms may also be used if a caregiver gives the injection.
 - Use a different injection site each time you use ENTYVIO.
 - Do not give an injection into moles, scars, bruises, or skin that is tender, hard, red, or damaged.
 - If you are not able to inject ENTYVIO at your regular scheduled time or you miss a dose of ENTYVIO, inject the dose as soon as possible. Then, inject your next dose every 2 weeks thereafter. If you are not sure when to inject ENTYVIO, call your healthcare provider.
 - If you take more ENTYVIO than you were told to take, call your healthcare provider.

What are the possible side effects of ENTYVIO?

ENTYVIO may cause serious side effects, see “What is the most important information I should know about ENTYVIO?”

The most common side effects of ENTYVIO include: common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, pain in extremities, and with injections under the skin: pain, swelling, itching, hives, bruising, rash, or redness at the injection site.

These are not all of the possible side effects of ENTYVIO.

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 ENTYVIO?

- Store ENTYVIO in a refrigerator between 36°F to 46°F (2°C to 8°C).
- If needed, the prefilled syringe or prefilled pen can be left out of the refrigerator 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 or prefilled pen if left out of the refrigerator for more than 7 days or left in direct sunlight.
- Do not freeze ENTYVIO. Do not use ENTYVIO if it has been frozen.
- Keep ENTYVIO in the original package to protect from light until the time of use.
- ENTYVIO prefilled syringe or prefilled pen is not made with natural rubber latex.

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

General information about the safe and effective use of ENTYVIO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ENTYVIO for a condition for which it was not prescribed. Do not give ENTYVIO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ENTYVIO that is written for health professionals.

What are the ingredients in ENTYVIO?

Active ingredient: vedolizumab

Inactive ingredients in vial for intravenous infusion: arginine hydrochloride, histidine, histidine monohydrochloride, polysorbate 80 and sucrose

Inactive ingredients in prefilled syringe or prefilled pen for subcutaneous injection: arginine hydrochloride, citric acid monohydrate, histidine, histidine monohydrochloride, polysorbate 80, sodium citrate dihydrate, and Sterile Water for Injection

Manufactured by: **Takeda Pharmaceuticals U.S.A., Inc.**

Cambridge, MA 02142

U.S. License No. 1898

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All other trademark names are the property of their respective owners.

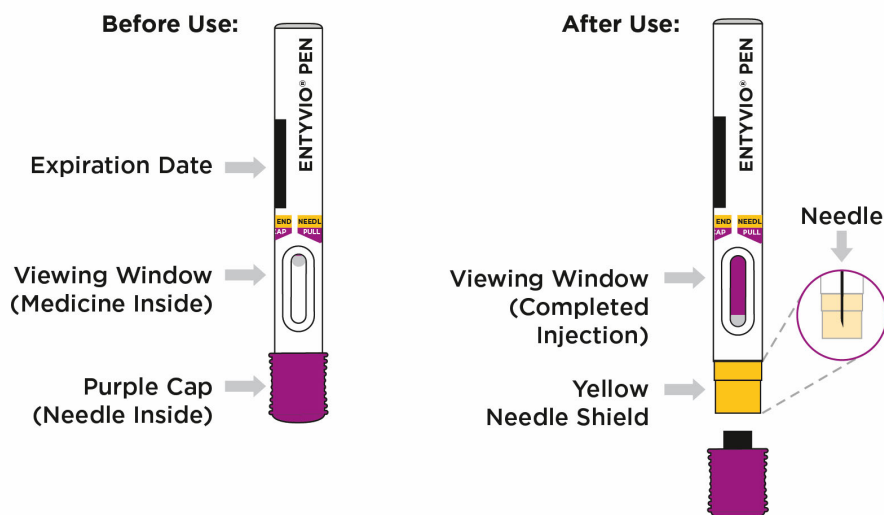
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For more information, go to www.ENTYVIO.com or call 1-877-TAKEDA7 (1-877-825-3327).

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.

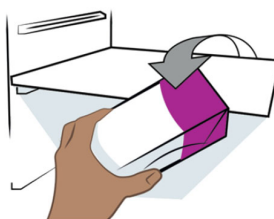


Figure A

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")

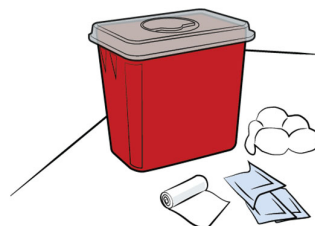


Figure C

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**.

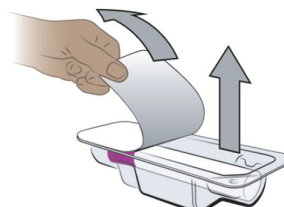


Figure E

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.

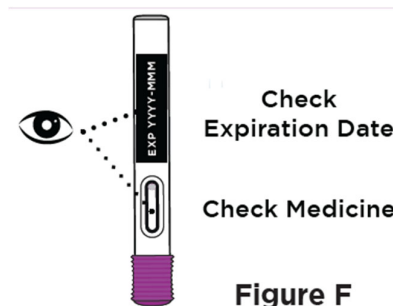


Figure F

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.

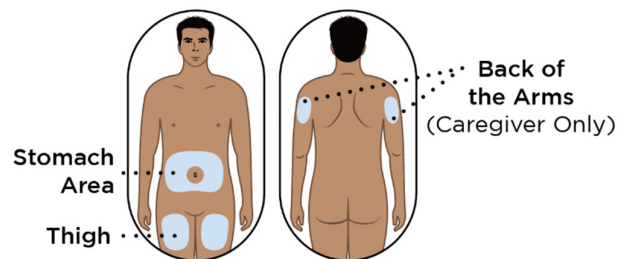


Figure G

- **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.

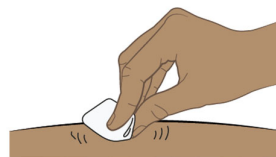


Figure H

Continue to **Step 9** →

Injecting ENTYVIO

Step 9. Remove the 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.

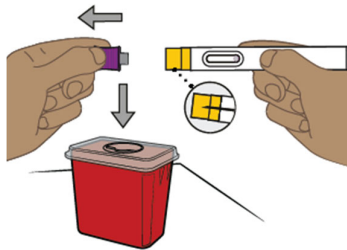


Figure I

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.

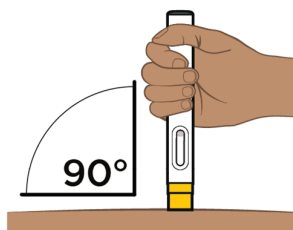


Figure J

Step 11. Start injecting ENTYVIO

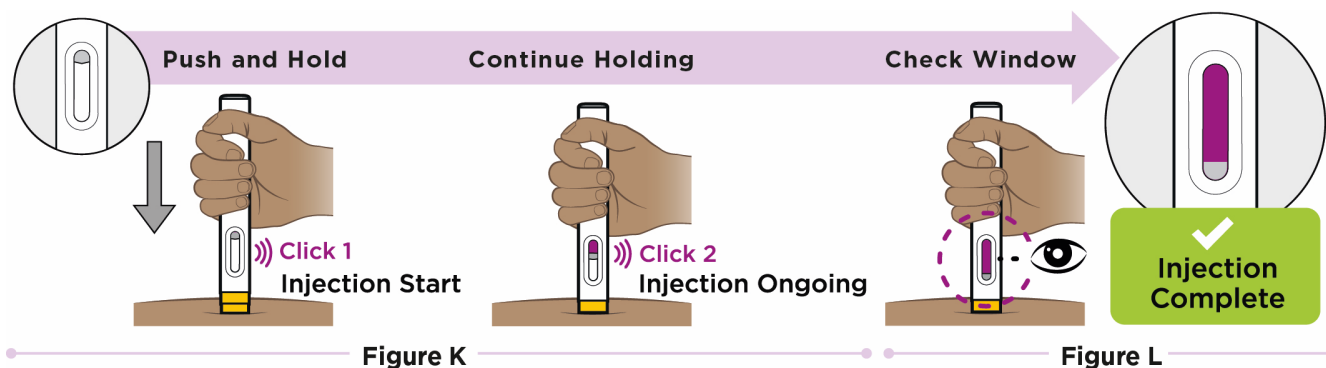
Push the prefilled pen straight down and hold for at least 10 seconds (see **Figure K**).

- 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

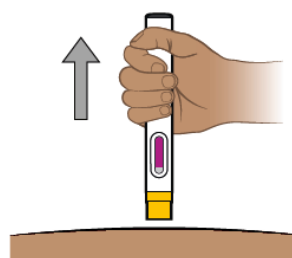
Continue holding the prefilled pen with constant pressure until **the viewing window has filled with purple to make sure you have received your full dose** (see **Figure L**).

- 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>.

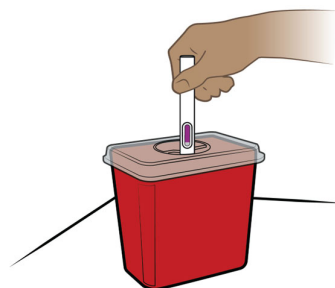


Figure N

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

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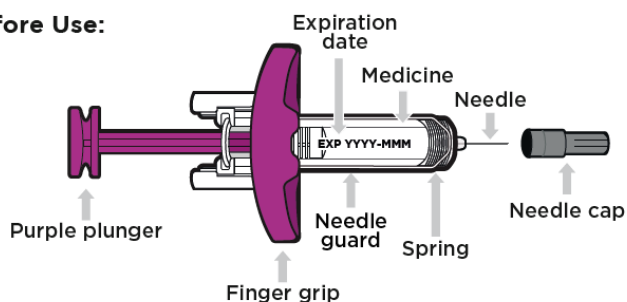
This Instructions for Use has been approved by the U.S. Food and Drug Administration.
 Approved: 9/2023

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

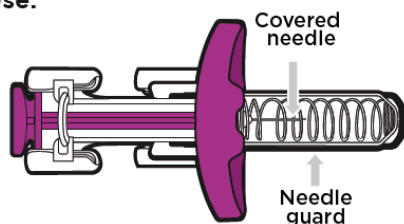
This Instructions for Use contains information on how to inject ENTYVIO.

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.

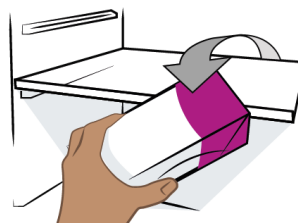


Figure A

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”)

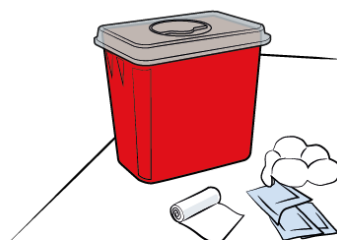


Figure C

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**.

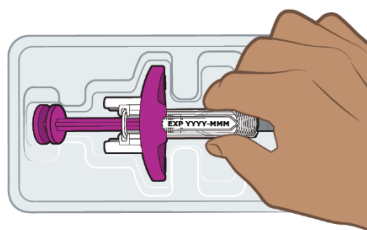


Figure E

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.

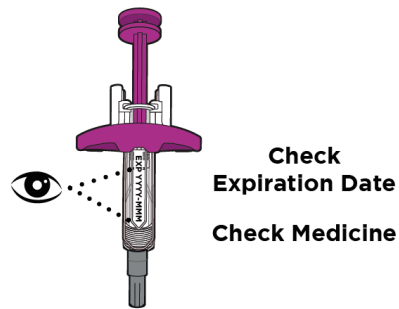


Figure F

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.

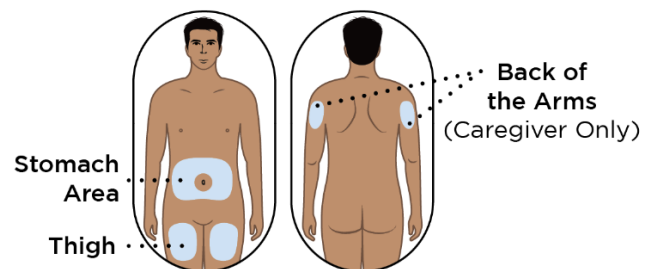


Figure G

- **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.

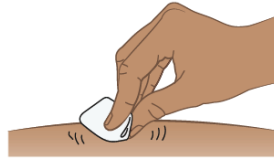


Figure H

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.

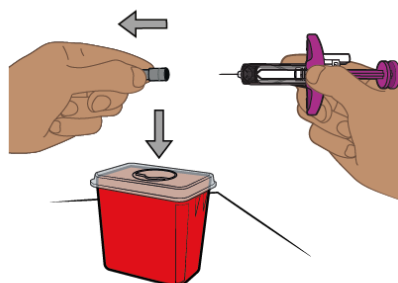


Figure I

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.

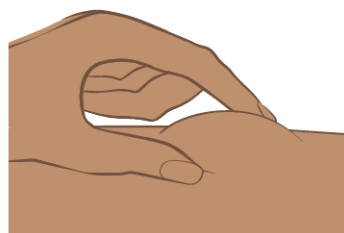


Figure J

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.

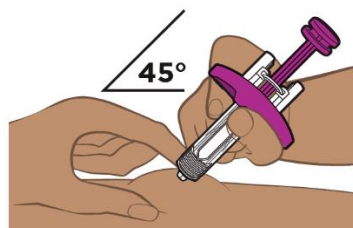
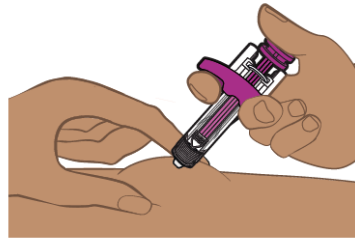


Figure K

Step 12. Push down on the plunger

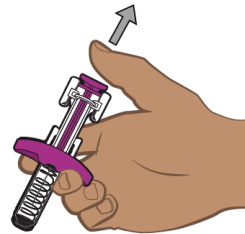
Push the plunger all the way down until all the medicine is injected (see **Figure L**).

- **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>.

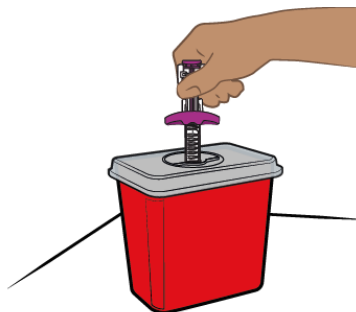


Figure N

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

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