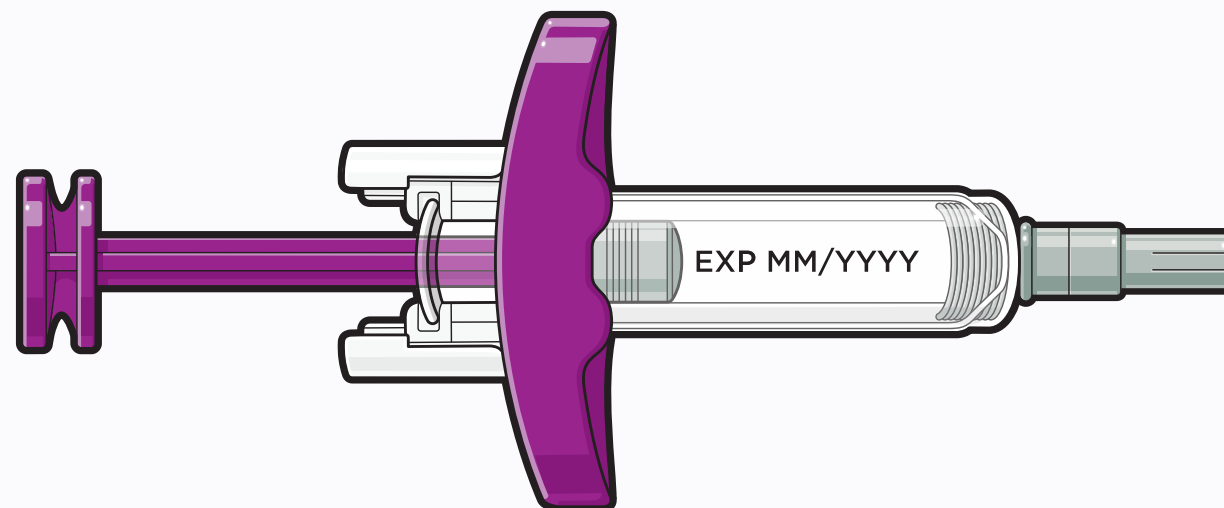


Quick Guide to the Prefilled Syringe



Uses of ENTYVIO® (vedolizumab):

ENTYVIO is a prescription medicine used in adults **with moderate to severe active ulcerative colitis (UC) when certain other UC medicines have not worked well enough or cannot be tolerated.**

ENTYVIO may begin helping some of your symptoms. For people who respond to ENTYVIO, it may help to induce and maintain remission, reduce or stop the use of corticosteroid medicines, and improve the way the lining of your large intestine looks to your healthcare provider during colonoscopy.

Safety Considerations

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. ENTYVIO may cause serious side effects including infusion or injection and serious allergic reactions while receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of serious infections.

Please see Important Safety Information on pages 9 and 10.

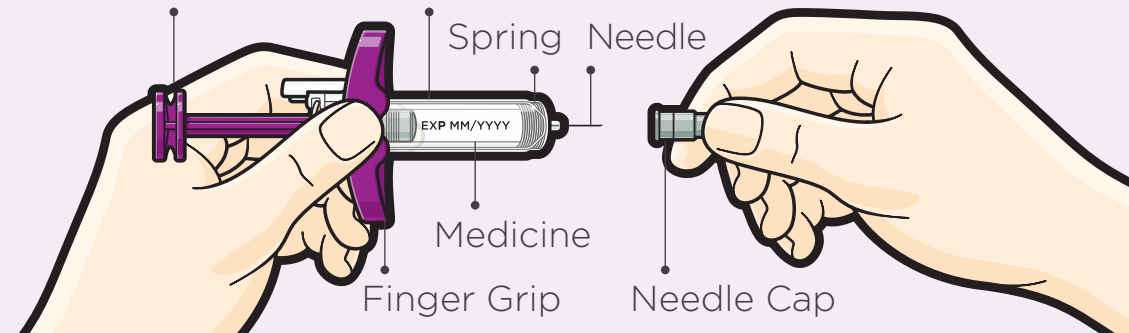
Meet the Prefilled Syringe

The device is designed for one-time use and is prefilled with a single dose of medication.

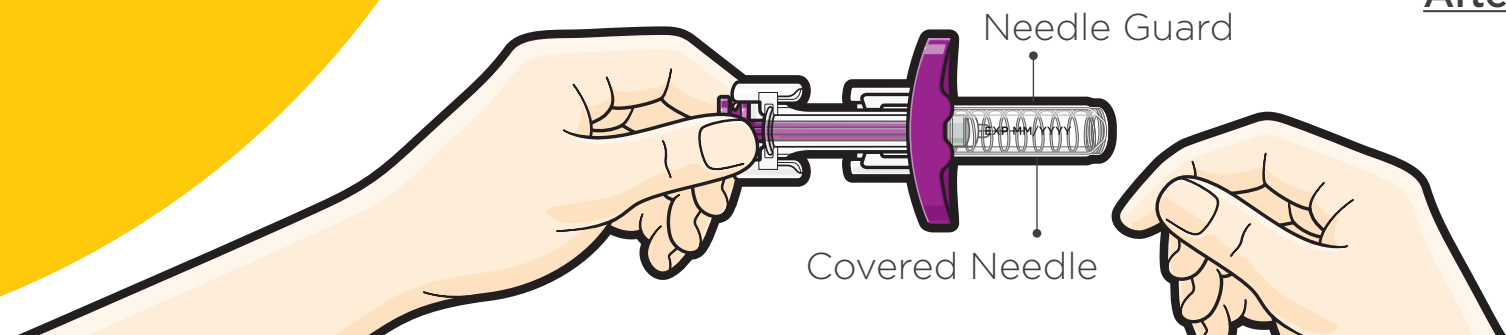
- The **expiration date** is printed on the syringe.
- It has a **needle cap** that you remove before injection.
- After you inject, a **needle guard** will automatically cover the needle.



Purple Plunger Needle Guard Spring Needle Before Use



After Use



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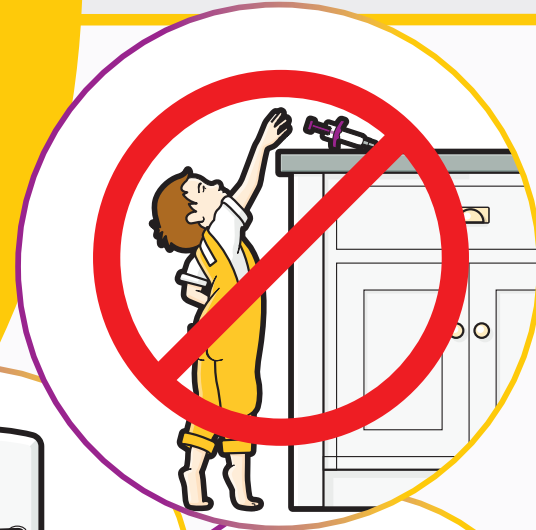
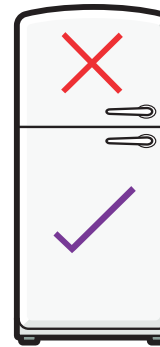
Before You Begin

Your single-dose prefilled syringe will come with detailed **Instructions for Use**, so be sure to review them! Here are some additional things to know.

- Always keep syringes and disposal containers **out of reach of children**.
- Store your prefilled syringe boxes in the refrigerator, but **do not freeze**.
- If needed, you can keep the syringe in its box at room temperature (up to 77°F) for up to 7 days, but **do not leave in direct sunlight**.

Most important, if you have any questions or concerns about the prefilled syringe, call your healthcare provider.

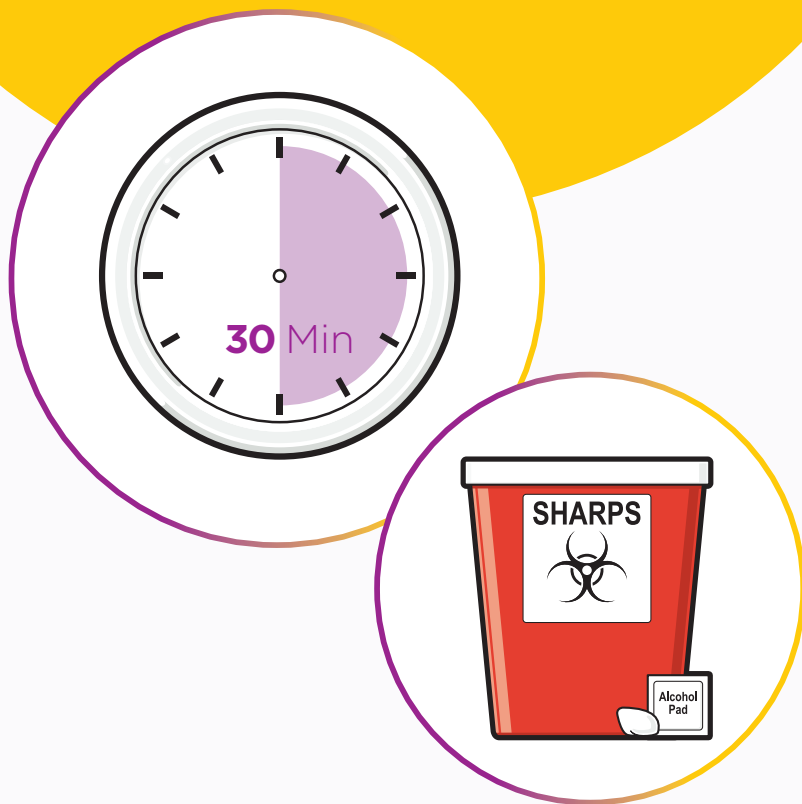
You can also call **1-844-ENTYVIO**.



Safety Considerations

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Get Everything Ready



Start by finding a clean, flat surface for all your supplies.

Then get a prefilled syringe box out of the refrigerator.

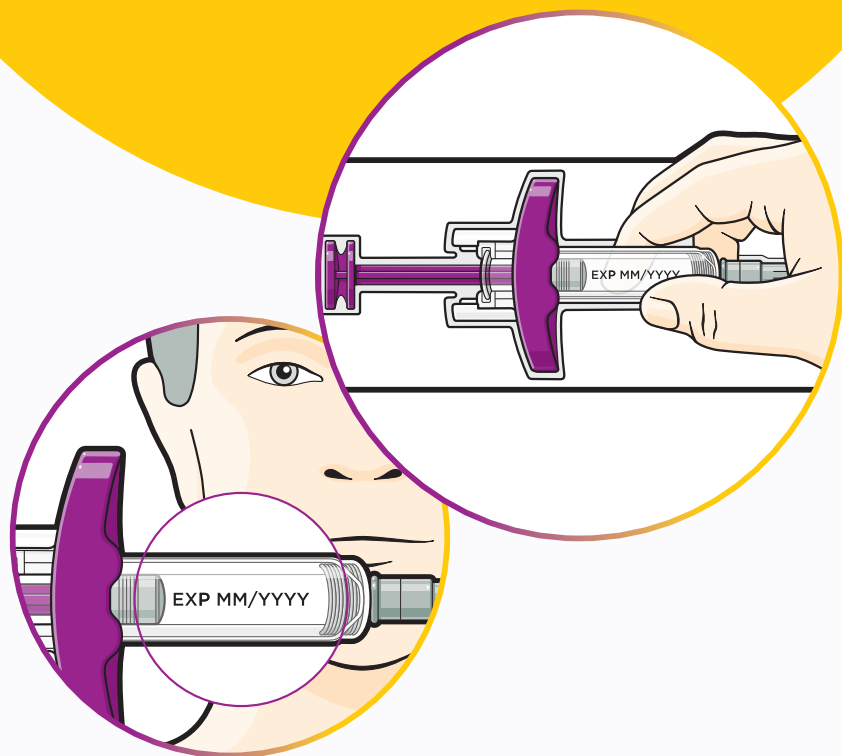
- **Do not use** if any of the seals on the box are broken or missing.
- **Check the expiration date** on the box and do not use if the date has passed.
- **Important: Wait 30 minutes to let the pen come to room temperature (up to 77°F).** Don't warm the pen in any other way, keep it out of direct sunlight, and leave it in the tray until you are ready to inject.
- **Gather other things you'll need** while you wait: an alcohol pad, a cotton ball or gauze and the sharps disposal container.

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Please see Important Safety Information on pages 9 and 10.

Inspect Your Syringe



Before you do anything, wash your hands!

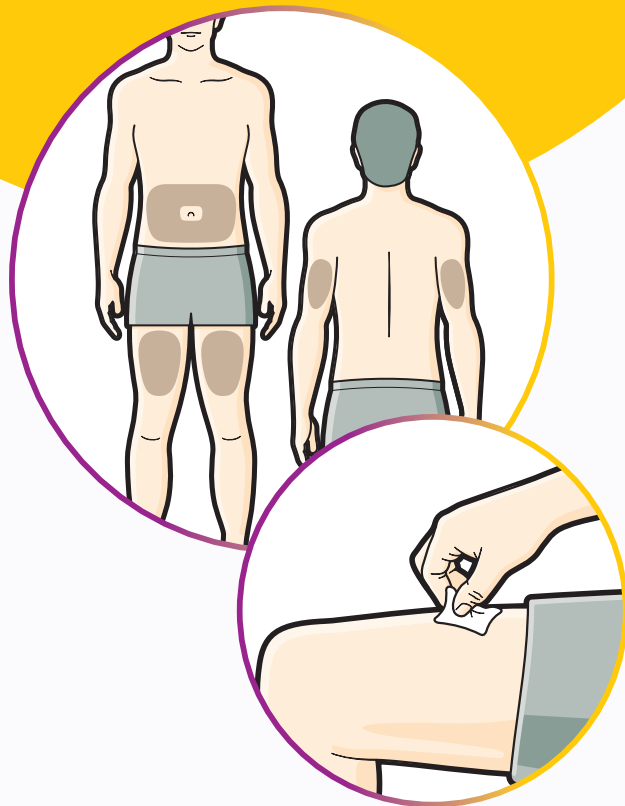
Then peel back the paper on the tray to lift the syringe out for inspection.

- **Don't touch or lift** from the purple plunger, or remove the needle cap.
- **Do not use if** you see any damage or if the expiration date has passed.
- Look at the medicine inside the syringe body. **It should be colorless to yellow.**
- **Do not use if** the medicine is cloudy or has particles floating in it.
- **Do not shake!** Seeing some air bubbles is normal.

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Prepare for Injection



You're almost ready!

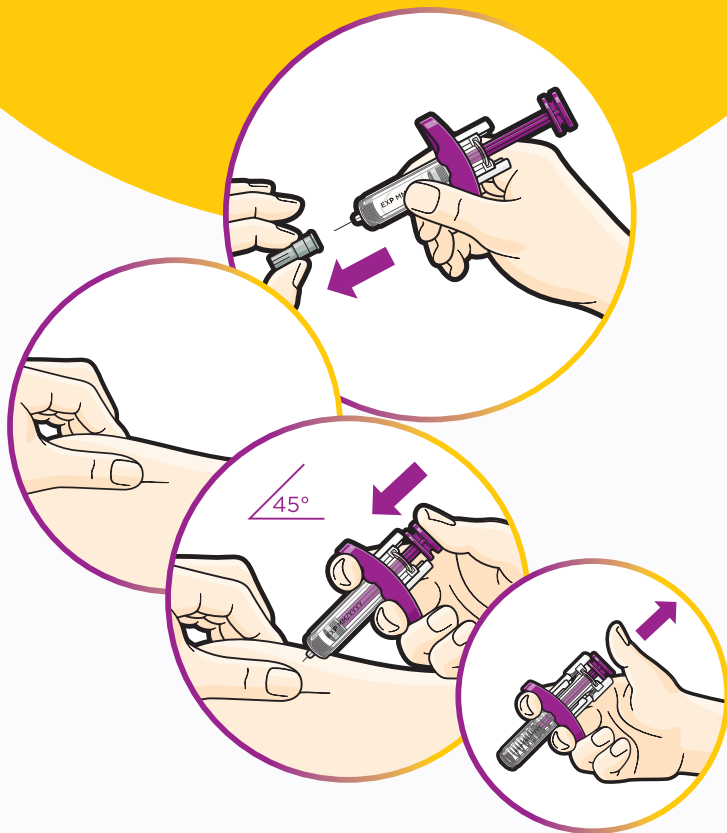
- First, decide on an injection site.
- You can inject on the front of the thighs or stomach area (except for 2 inches around the belly button). Or a caregiver can give you an injection on the back of the upper arm.
- Always inject on bare skin, and choose a different spot than your last injection. You should avoid injecting into moles, scars, bruises, or skin that is tender, hard, red or damaged.
- Wipe the site with an alcohol pad and let it dry. Don't touch the area again until after you inject.

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Please see Important Safety Information on pages 9 and 10.

Inject the Medicine



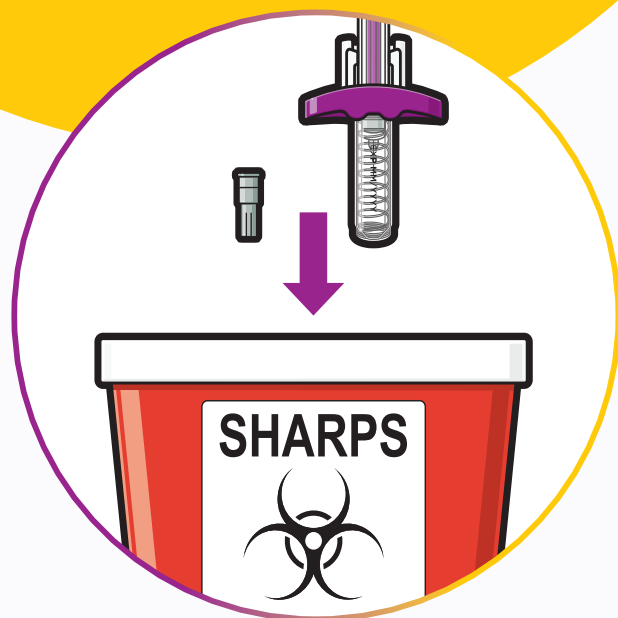
It's go time! Just follow these steps.

- Pull the needle cap straight off, but don't touch or pull back the purple plunger. You may see a drop of liquid at the end of the needle.
- Don't touch or re-cap the needle, or use it if the needle is bent or broken, or the syringe has been dropped. Throw away the cap.
- Hold the prefilled syringe in one hand and pinch the skin around the injection site with the other. Hold until the injection is completed.
- Insert the needle at a 45-degree angle all the way into the pinched skin.
- Push the plunger as far as it will go to inject all the medicine.
- Keep pressure on the plunger and remove the needle from your skin.
- Take your thumb off the plunger to allow the needle guard to cover the needle.
- If you see a little amount of blood on the skin, press with cotton ball or gauze.

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Clean Up Safely



Throw your device away the right way, right away.

It's important that you dispose of the used syringe in the sharps disposal container provided right after use. **Do not recycle.** The other supplies, including the needle cap, can be put in the household trash.

Note: If an FDA-cleared container is not available, a heavy-duty plastic household container, like a laundry detergent container can be used as an alternative.

Safety first!

Always keep the prefilled syringe and the sharps disposal container **out of reach of children.** When the container is almost full, follow community guidelines, and state and local laws regarding disposal.

For more information, including specific information about sharps disposal in your state, visit <http://www.fda.gov/safesharpsdisposal>.

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Please see Important Safety Information on pages 9 and 10.



Important Safety Information about ENTYVIO® (vedolizumab)

- Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients.
- ENTYVIO may cause serious side effects, including:
 - Infusion or injection and serious allergic 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 immediate medical help 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).
 - ENTYVIO may increase your risk of getting a serious infection. Before receiving and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or 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.
 - It may be possible for a person to get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). People with weakened immune systems can get PML, which 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 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 abdomen, dark urine, or yellowing of the skin and eyes (jaundice).



Important Safety Information (continued)

- 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, and pain in extremities and pain, swelling, redness or itching at the injection site (with injections under the skin). These are not all the possible side effects of ENTYVIO. Call your healthcare provider for medical advice about side effects.
- Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you: have or think you may have an infection or have infections that keep coming back; have liver problems; have tuberculosis (TB) or have been in close contact with someone with TB; have recently received or are scheduled to receive a vaccine; or if you are pregnant, breastfeeding, plan to become pregnant, or plan to breastfeed.

Please see accompanying Full Prescribing Information, including the Medication Guide, for ENTYVIO in pocket and talk with your healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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ENTYVIO is a prescription medicine used in adults:

- **with moderate to severe active ulcerative colitis (UC) when certain other UC medicines have not worked well enough or cannot be tolerated:**
 - to begin helping some of your symptoms
 - in people who respond to ENTYVIO, to help get UC under control (induce remission) and keep UC under control (maintain remission)
 - for people who respond to ENTYVIO, you may be able to reduce or stop the use of corticosteroid medicines
 - to improve the way the lining of your large intestine looks to your healthcare provider during colonoscopy



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