

Quick Guide to Using the EntyvioPEN



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

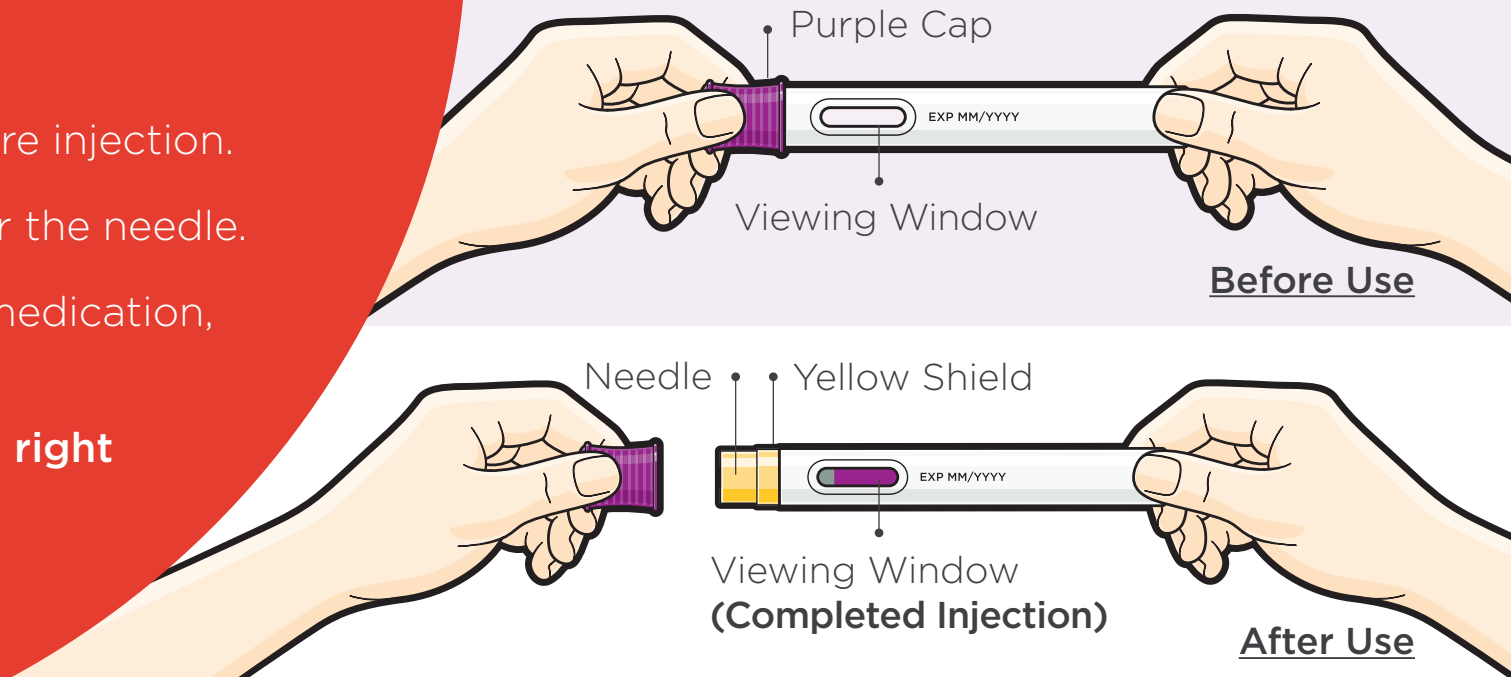
Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. ENTYVIO may cause serious side effects including infusion or injection and serious allergic reactions while receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of serious infections.

Please see Important Safety Information on pages 9 and 10.

Meet the EntyvioPEN

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

- It has a **purple cap** that you remove before injection.
- After you inject, a **yellow shield** will cover the needle.
- Use the **viewing window** to inspect the medication, and check if your injection is complete.
- **Remember: Do not remove the cap until right before you are ready to inject.**



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Before You Begin

Your EntyvioPEN will come with detailed Instructions for Use, so be sure to review them! Here are some additional things to know.

- Always keep pens and disposal containers **out of reach of children**.
- Store your EntyvioPEN boxes in the refrigerator, but **do not freeze**.
- If needed, you can keep the pen in its box at room temperature for up to 7 days, but **do not leave in direct sunlight**.

Most important, if you have any questions or concerns about the EntyvioPEN, call your healthcare provider. You can also call **1-844-ENTYVIO**.

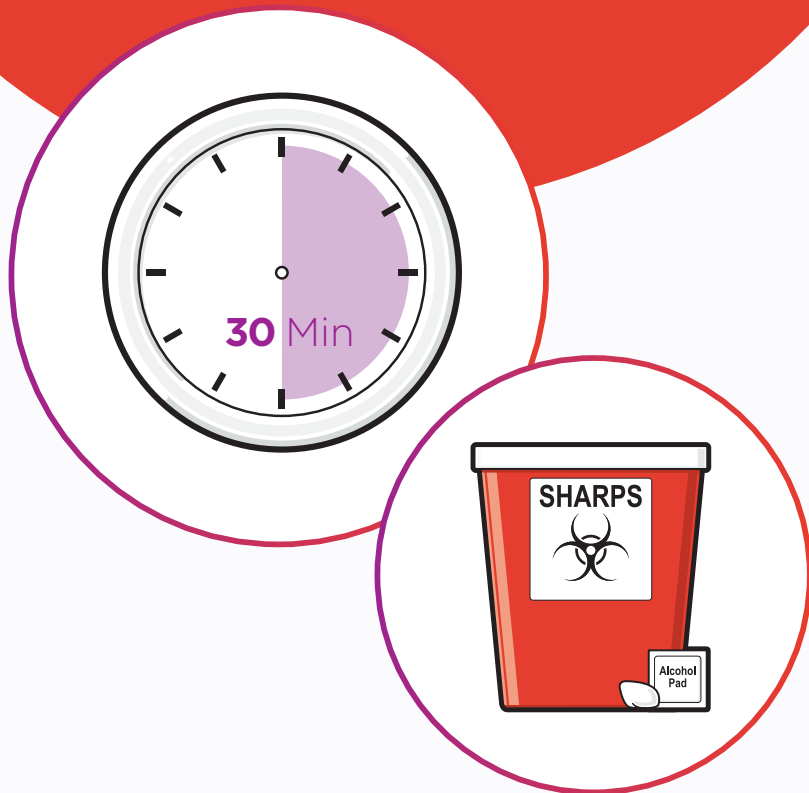


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Get Everything Ready



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

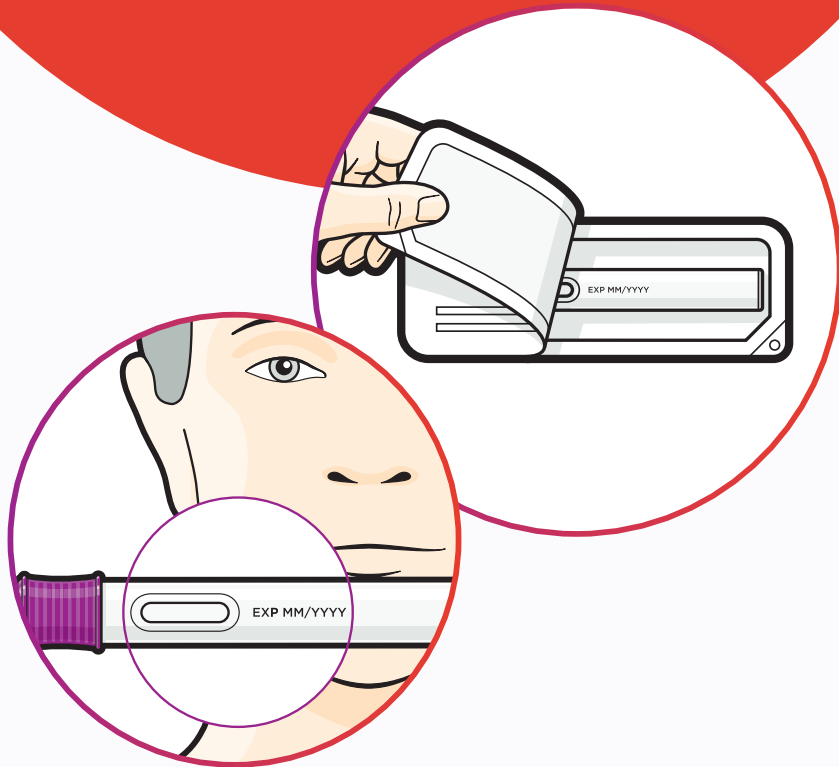
Then get a prefilled pen box out of the refrigerator.

- **Do not use** if any of the seals on the box are broken or missing. Note: There may be a small gap between the cap and the pen. This is normal.
- **Check the expiration** date on the box and do not use if it 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 a sharps disposal container.

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Inspect Your Pen



Before you do anything, wash your hands!

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

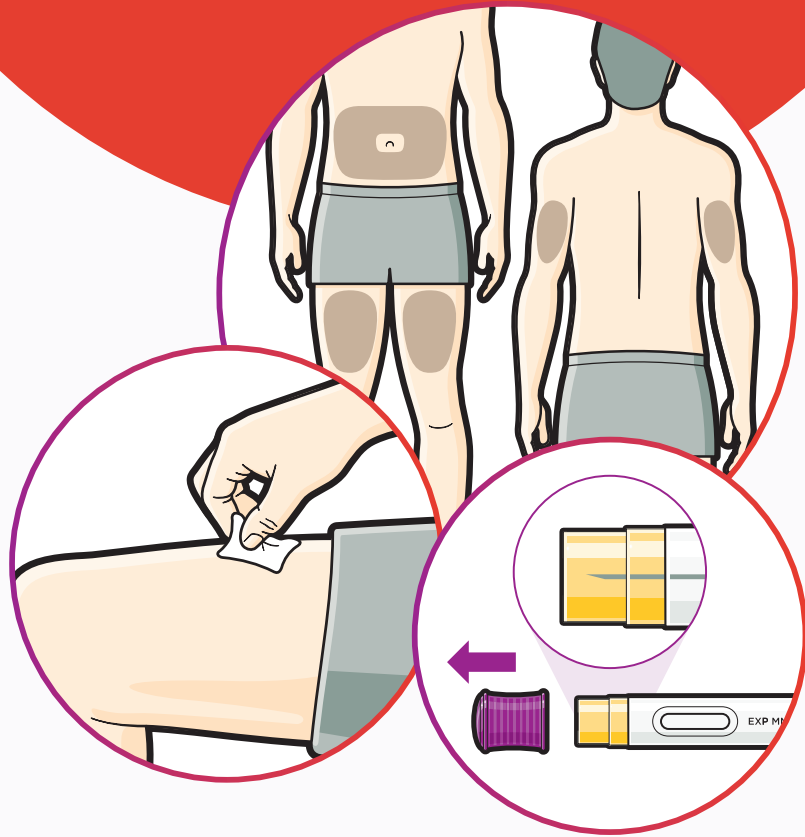
- **Do not use if** you see any damage or if the expiration date has passed.
- Look at the medicine in the viewing window. **It should be colorless to yellow.**
- **Do not use if** the medicine is cloudy or has particles floating in it.
- **Do not shake!** Seeing some air bubbles is normal.

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Prepare for Injection



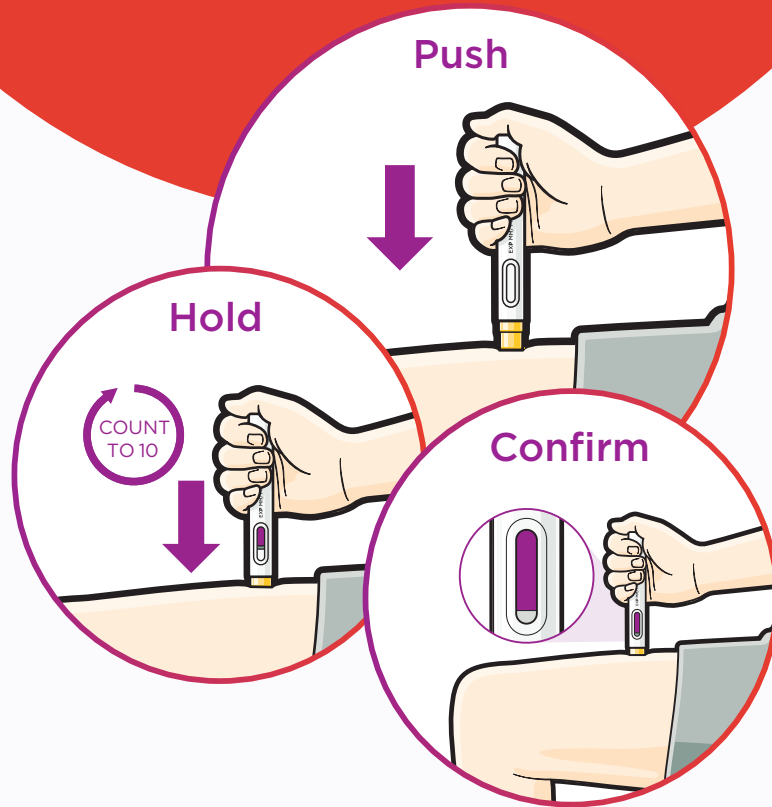
You're almost ready!

- 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.
- Pull the purple pen cap straight off and throw it away.
- **Important:** Don't press your thumb, fingers or hand over the yellow needle shield, don't re-cap the prefilled pen, and never use a pen that has been dropped.

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Inject the Medicine



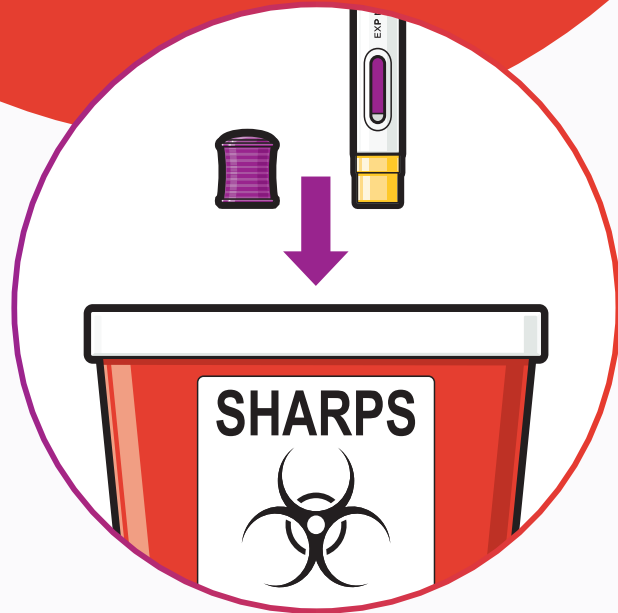
It's go time! Just follow these steps.

- Pick up the pen with the viewing window showing.
- Place at a 90-degree angle to the injection site, yellow side down. Do not push down until you are ready to inject.
- Push down on the prefilled pen as far as it will go to begin the injection.
- Hold and count to 10 using constant pressure to allow all the medication to be injected. You may hear two clicks at the start and near the end of the injection.
- Even if you hear clicks, confirm that the viewing window is filled with purple before you stop pushing (a small amount of gray is normal).
- Lift the pen from the injection site. A yellow shield will lock over the needle. If you see a little blood on the skin, just press with a cotton ball or gauze.
- If the viewing window did not fill completely, call your healthcare provider as you may not have received your full dose of medicine.

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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 pen in the sharps disposal container provided right after use. **Do not recycle.** The other supplies, including the pen top, 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 the EntyvioPEN 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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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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