

Demonstration Video: Injecting with the Single Dose Vial

VO:

LORIE: Oh! Hey there - the single-dose vial demo video will begin after this brief safety message.

INDICATIONS:

Prescription Enbrel® (etanercept) single-dose vial.

The video you are about to see is intended to provide you with an overview and basic information about the ENBREL single-dose vial. This video is not a comprehensive review of ENBREL single-dose vial and does not replace the Instructions for Use. Please review with your healthcare provider the Patient Instructions for Use included with ENBREL single-dose vial. Be sure to talk to your healthcare provider about any questions or concerns you may have about the ENBREL single-dose vial.

The Important Safety Information, including Boxed Warning for ENBREL, will be discussed later in this video.

ENBREL is indicated for reducing signs and symptoms, keeping joint damage from getting worse, and improving physical function in patients with moderately to severely active rheumatoid arthritis. ENBREL can be taken with methotrexate or used alone.

ENBREL is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in children 2 years of age or older.

ENBREL is indicated for reducing signs and symptoms, keeping joint damage from getting worse, and improving physical function in adult patients with psoriatic arthritis. ENBREL can be used with or without methotrexate.

ENBREL is indicated for active juvenile psoriatic arthritis (JPsA) in children 2 years of age or older.

ENBREL is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

ENBREL is indicated for chronic moderate to severe plaque psoriasis (PsO) in children 4 years of age or older and adults who may benefit from taking injections or pills (systemic therapy) or phototherapy (ultraviolet light).

Individual results may vary. Talk to your doctor about the possible risks and benefits of ENBREL.

Please see Important Safety Considerations later in this video and the Important Safety Information, including Boxed Warning, on this webpage. Please also see the full Prescribing Information and Medication Guide available on this website.

MARY: Coming!

LORIE: Mary?

MARY: Hi!

LORIE: Hi, I'm Lorie, your ENBREL[®] Nurse Partner.

MARY: Hi, Lorie. Come on in! Thanks for coming over.

LORIE: Absolutely, my pleasure.

LORIE: So, as you know, I'm here to help you as you get started with the ENBREL single-dose vial. Think of today as a demonstration that can help supplement the training that you received in your physician's office. Now, I'll go over things in detail. But before I do, your single-dose vial came with an Instructions for Use.

MARY: Yup, I have one. I reviewed it with the nurse when we received training in the office, and I read it all the way through just before you came over. I'm really glad you're here, because this is the first time I'm injecting myself at home.

LORIE: Of course. And you should always read the Instructions for Use before injecting and refer to it if you have any questions.

MARY: Perfect.

LORIE: Alright, are you ready to get started?

MARY: Ready.

LORIE: Now, before you do the actual injection, I want to show you some features of the single-dose vial. Let's start with the vials.

MARY: Great.

LORIE: Each one holds .5 milliliters of medicine. If your prescribed dose is .5 milliliters or less, you'll need one vial. If your prescribed dose is more than .5 milliliters, you'll need two vials.

MARY: My prescription is for 1 milliliter a week, so I'll need two vials.

LORIE: Exactly. You'll also need one short needle for injecting, one long needle to withdraw the medicine from the vials, and a one milliliter syringe. You can use the same syringe to withdraw the medicine from each vial. But only use the syringe one time when it comes to your injection. There are three things you should always check before you begin. Make sure your vials haven't expired, make sure the green cap is attached, and make sure the medicine inside doesn't look lumpy, discolored, or cloudy. Now look inside, see how the medicine looks?

MARY: It's clear and colorless. I do see some small white particles though.

LORIE: And you may see tiny white particles sometimes, but not always. Just make sure it never looks lumpy, discolored, or cloudy—if it does, don't use it. Contact your doctor, or you can call 1-888-4ENBREL to get a replacement.

MARY: Noted.

LORIE: So, where's your ENBREL single-dose vial now?

MARY: In my fridge. I put it in there right after I got it.

LORIE: Perfect. Let's go get your single-dose vials out of the fridge now.

MARY: Okay. Follow me. I need to warn you - my fridge is a bit messy. Don't judge.

LORIE: No worries! You should see my fridge! I see you keep your single-dose vials on the top shelf. That's perfect. You want to keep it out of reach of children. Couple quick things to keep in mind, never freeze it or store it in extreme heat or cold. Don't shake it. And always store it in its original carton, like you have. That protects it from light damage. And remember to keep your unused vials in the refrigerator. Now take your single-dose vials out of the fridge. Then wait. You want this to get to room temperature. Injecting at room temperature can make for a more comfortable injection. So, let it sit out for about 30 minutes. You can take a walk. Stream a show. Just make sure it's out of reach of children and pets.

MARY: Ah, I know just the place.

LORIE: Perfect.

MARY: Oh, question, I'm going to be going out of town. And I don't know if the hotel will have a refrigerator or anything. Can I travel with ENBREL?

LORIE: Absolutely. ENBREL can actually be at room temperature for up to 30 days. So you can actually bring it with you in your carry-on, and keep taking it right on schedule.

MARY: That's perfect.

LORIE: But for today, let's just do 30 minutes.

MARY: Okay.

LORIE: Oh, one more thing. Once ENBREL comes to room temperature, do not put it back in the refrigerator.

MARY: Got it. Wow, that was a fast 30 minutes.

LORIE: Well, first things first, let's wash your hands thoroughly.

MARY: Well, I'm all set.

LORIE: Alright, let's get your vials down.

MARY: Okay.

LORIE: This is what you'll need. A 1 milliliter syringe, the long needle for withdrawal, the short needle for injecting, alcohol wipes, cotton balls, bandage, and of course the sharps container for disposal. The first thing you're going to do is pop off the green caps. Take two alcohol wipes to wipe down each of the gray stoppers here. Twist the long needle onto the syringe. Remove the needle cover. Now, pull back the plunger to the 0.5 milliliter mark. Okay, so hold the vial firmly and insert the needle into the gray stopper. Just like that. Now this is important, keep the needle above the medicine for now. Slowly push .5 milliliters of air into the vial. Okay, tilt the vial at a 45-degree angle - like this. And now keep the needle tip below the medicine to avoid pulling air into the syringe. Then slowly pull back the plunger and fill the syringe, and make sure you got all the medicine out. Now, let's gently tap the syringe, just like you see in movies. This gets the air bubbles and air pockets to the top. After the air bubbles rise to the top, carefully push the plunger until they're pushed out. A small amount of tiny air bubbles are okay. Even though some medication may be spilled out make sure you have enough for your prescribed dose. Okay, now let's do the other vial. So, you want to insert the same needle in. And then tilt the vial at a 45-degree angle. Perfect. Then slowly pull back the plunger and fill the syringe. And make sure you got all the medicine out. Then tap the syringe again to have the air bubbles and air pockets rise to the top. Push the plunger to get rid of the air. Then push the plunger to your prescribed dose. For you that's 1 milliliter. Let's recap the needle for now, using this nifty technique called the 1-handed scoop method. Slide the needle into the cap and scoop upwards. Just like that! Now we can prepare the syringe to inject your medicine. So, let's remove the long needle by twisting it off and replace it with the short needle by twisting it on. We don't need the long needle anymore, so throw it away in your FDA-cleared sharps disposal container. So today you'll be injecting into your thigh, but you can see other injection areas in your Instructions for Use. Let's use another alcohol wipe to clean the injection area. That's great. Now let it dry, and don't touch that area again until you're ready to inject.

MARY: Got it.

LORIE: Now pinch your skin gently. Perfect, just like that. Now at a 45-degree angle, firmly and quickly insert the needle into the skin. Then slowly push the plunger down, all the way down. Yup, just like that.

MARY: Okay, all the way down.

LORIE: Perfect. When the syringe is empty, remove it from your skin. You'll want to put the syringe and the needle in a sharps container.

MARY: Okay.

LORIE: There's no medicine in it anymore, but there is still a needle. So you can't just throw it away in your household trash or recycling. Great, now use a cotton ball and press lightly on the injection site.

MARY: I'll put a bandage on as well.

LORIE: One more thing, if you think you didn't receive your full dose, call your doctor.

MARY: Thanks Lorie. It was helpful having you here today.

LORIE: I'm so glad. Last thing we're going to do is dispose of your used single-dose vials safely. Even if there is some medicine in it, you can't use it a second time. Drop them in, seal it up and just make sure your kids and pets can't get to it

MARY: That's it?

LORIE: That's it.

MARY: Thanks so much for coming. I'm really much more comfortable now that we went over this.

LORIE: Of course, it's my pleasure. And remember to refer to your Instructions for Use if you have any questions. And you can also call ENBREL Support. We're happy to help!

MARY: Awesome. Bye now!

LORIE: Bye!

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ENBREL?

ENBREL is a medicine that affects your immune system. ENBREL can lower the ability of your immune system to fight infections. Serious infections have happened in patients taking ENBREL. These infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients have died from these infections. Your healthcare provider should test you for TB before you take ENBREL and monitor you closely for TB before, during, and after ENBREL treatment, even if you have tested negative for TB.

There have been some cases of unusual cancers, some resulting in death, reported in children and teenagers who started using tumor necrosis factor (TNF) blockers before 18 years of age. Also, for children, teenagers, and adults taking TNF blockers, including ENBREL, the chances of getting lymphoma or other cancers may increase. Patients with RA may be more likely to get lymphoma.

Before starting ENBREL, tell your healthcare provider if you:

- Have any existing medical conditions
- Are taking any medicines, including herbals
- Think you have, are being treated for, have signs of, or are prone to infection. You should not start taking ENBREL if you have any kind of infection, unless your healthcare provider says it is okay
- Have any open cuts or sores
- Have diabetes, HIV, or a weak immune system
- Have TB or have been in close contact with someone who has had TB
- Were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your healthcare provider if you are not sure
- Live, have lived in, or traveled to certain parts of the country (such as, the Ohio and Mississippi River valleys, or the Southwest) where there is a greater risk for certain kinds of fungal infections, such as histoplasmosis. These infections may develop or become more severe if you take ENBREL. If you don't know if these infections are common in the areas you've been to, ask your healthcare provider
- Have or have had hepatitis B
- Have or have had heart failure
- Develop symptoms such as persistent fever, bruising, bleeding, or paleness while taking ENBREL
- Use the medicine Kineret (anakinra), Orencia (abatacept), or Cytosan (cyclophosphamide)
- Are taking anti-diabetic medicines
- Have, have had, or develop a serious nervous disorder, seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome
- Are scheduled to have surgery
- Have recently received or are scheduled for any vaccines. All vaccines should be brought up-to-date before starting ENBREL. Patients taking ENBREL should not receive live vaccines

- Are pregnant, planning to become pregnant, or breastfeeding
- Have been around someone with chicken pox

What are the possible side effects of ENBREL?

ENBREL can cause serious side effects including: New **infections** or worsening of infections you already have; **hepatitis B** can become active if you already have had it; **nervous system problems**, such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes; **blood problems** (some fatal); new or worsening **heart failure**; new or worsening psoriasis; **allergic reactions**; **autoimmune reactions**, including a lupus-like syndrome and autoimmune hepatitis.

Common side effects include: Injection site reactions and upper respiratory infections (sinus infections).

In general, side effects in children were similar in frequency and type as those seen in adult patients. The types of infections reported were generally mild and similar to those usually seen in children.

These are not all the side effects with ENBREL. Tell your healthcare provider about any side effect that bothers you or does not go away.

If you have any questions about this information, be sure to discuss them 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.

Please see [Prescribing Information](#) and [Medication Guide](#) available on this website.



Manufactured by Immunex Corporation

Marketed by Amgen, Inc.

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