

Prefilled Syringe Instructional Guide for SIMLANDI[®] (adalimumab-ryvk) injection

INDICATIONS

SIMLANDI[®] is a prescription medicine called a tumor necrosis factor (TNF) blocker. SIMLANDI is given by injection under the skin and is used to reduce the signs and symptoms of moderate to severe rheumatoid arthritis (RA) in adults as well as other FDA-approved indications found in the Full Prescribing Information.

Important Safety Information for SIMLANDI[®] (adalimumab-ryvk) injection, for subcutaneous use

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

You should discuss the potential benefits and risks of SIMLANDI with your doctor. SIMLANDI is a TNF blocker medicine that can lower the ability of your immune system to fight infections. You should not start taking SIMLANDI if you have any kind of infection unless your doctor says it is okay.

- **Serious infections have happened in people taking adalimumab products. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections.** Your doctor should test you for TB before starting SIMLANDI, and check you closely for signs and symptoms of TB during treatment with SIMLANDI, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.
- **Cancer.** For children and adults taking TNF blockers, including SIMLANDI, the chances of getting lymphoma or other cancers may increase. There have been cases of unusual cancers in children, teenagers, and young adults using TNF blockers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. If using TNF blockers, including SIMLANDI, your chances of getting two types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life-threatening if treated; tell your doctor if you have a bump or open sore that doesn't heal.

The most common side effects of SIMLANDI include injection site reactions (pain, redness, rash, swelling, itching, or bruising), upper respiratory infections (sinus infections), headaches, and rash. These are not all the possible side effects with SIMLANDI. Tell your doctor if you have any side effect that bothers you or that does not go away.

Please read the [Full Prescribing Information](#), including [BOXED WARNINGS](#) and [Medication Guide](#).

How to Administer SIMLANDI with the Prefilled Syringe FOR SUBCUTANEOUS USE ONLY.

Before Injecting: Your healthcare provider should show you how to use SIMLANDI before you use it for the first time. Call your healthcare provider or 1-888-483-8279 if you have any questions.

You can use this guide to review the steps for your SIMLANDI injection. Read and follow the Instructions for Use to help you understand how to safely inject SIMLANDI with the Prefilled Syringe.

You can also find information on how to inject SIMLANDI with the Prefilled Syringe in the carton of your prescribed medication or at SIMLANDI.com. Call your healthcare provider for further assistance.

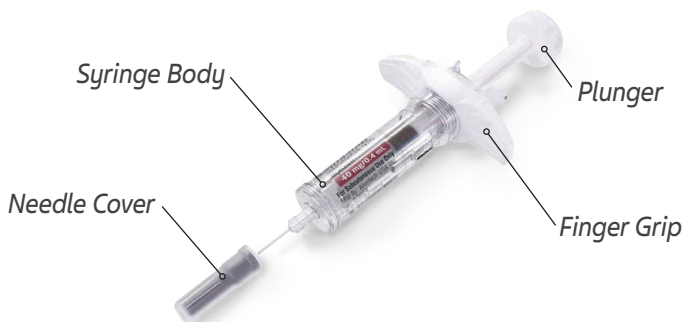
IMPORTANT

DO NOT use the Prefilled Syringe and call your healthcare provider or pharmacist if:

- Liquid is cloudy, discolored, or has flakes or particles in it.
- Expiration date has passed.
- Liquid has been frozen (even if thawed) or left in direct sunlight.
- The Syringe has been dropped or crushed.

About your Prefilled Syringe for SIMLANDI

Before you get started, it's important to get familiar with your Single-Dose Prefilled Syringe for SIMLANDI.



Keep the Needle Cover on until right before your injection.

Keep SIMLANDI, injection supplies, and all other medicines out of reach of children.

Storage conditions

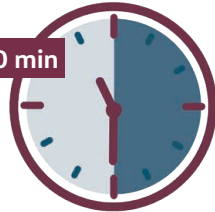
- Store SIMLANDI in the refrigerator between 36°F to 46°F (2°C to 8°C). If needed, SIMLANDI can be stored at room temperature up to 77°F (25°C) for up to **30 days**.
- Throw away SIMLANDI if it has been kept at room temperature and not used within **30 days**.
- Keep SIMLANDI in the original carton until use to protect it from light.
- **Do not freeze** or store SIMLANDI in extreme heat or cold.
- Refrigerated SIMLANDI may be used until the expiration date.
- Record the date you first remove SIMLANDI from the refrigerator in the spaces provided on the carton.

Prepare

Read instructions on all pages before using the SIMLANDI Single-Dose Prefilled Syringe

Take the Prefilled Syringe for SIMLANDI out of the refrigerator

15 to 30 min



Leave the Prefilled Syringe at room temperature, in a place out of the reach of children or pets, for **15 to 30 minutes** before injecting.

Do not remove the Needle Cover while allowing the Prefilled Syringe to reach room temperature.

Do not warm the Prefilled Syringe in any other way. For example, **do not** warm it in a microwave or in hot water.

Do not use the Prefilled Syringe if liquid has been frozen (even if thawed).

Inspect the Prefilled Syringe

- Check the label and expiration date.
- Check that the liquid is clear and colorless.

Do not use the Prefilled Syringe if:

- The expiration date has passed.
- The liquid is cloudy, discolored, or has flakes or particles in it.
- It has been dropped or crushed.

Gather your supplies on a clean flat surface

- 1 Single-Dose Prefilled Syringe for SIMLANDI.
- 1 alcohol swab.
- 1 cotton ball or gauze pad.
- Puncture-resistant sharps disposal container.



Prefilled Syringe
for SIMLANDI



Alcohol Swab
and Cotton Ball



Sharps
Container

Wash and dry your hands

Choose injection site

- On the front of your thighs or your abdomen at least 2 inches from your navel (belly button).
- Choose a different site each time you give yourself an injection.



Clean the injection area

- Use an alcohol swab to clean the area in a circular motion where you want to inject.

Do not:

- Inject through clothes.
- Inject into skin that is sore, bruised, red, hard, scarred, has stretch marks, or areas with psoriasis plaques.

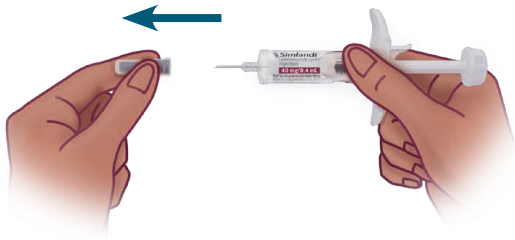
Inject

Injecting with the Prefilled Syringe is a two-step process: Insert and Push.

Step 1: INSERT

Do not remove the cover from the Prefilled Syringe until you are ready to inject.

- Gently pull the Needle Cover straight off

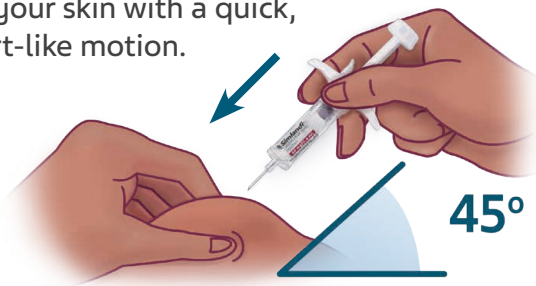


Do not recap. **Do not** touch the needle with your fingers or let the needle touch anything. **Do not** pull back on the Plunger at any time.

- **Hold** the body of the Prefilled Syringe in one hand between the thumb and index fingers, like a pencil.
- Gently squeeze the skin around your injection site to make a raised area. Hold the skin firmly until the needle has been completely inserted.

Insert the Prefilled Syringe at a 45° angle

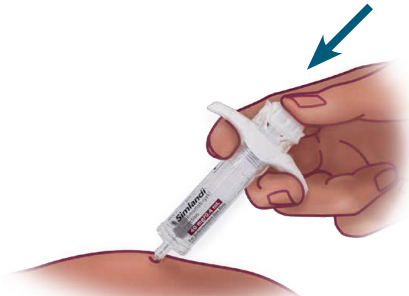
to your skin with a quick, dart-like motion.



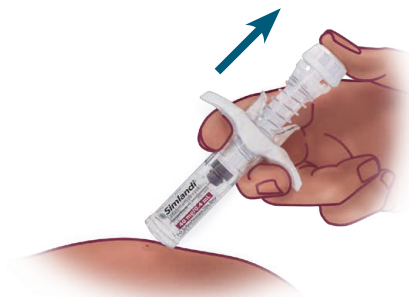
- After the needle is in, let go of the skin.

Step 2: PUSH

Slowly push the Plunger all the way in until all of the liquid is injected, and the Prefilled Syringe is empty.



- **When the injection is done**, slowly lift your finger from the Plunger. This empty syringe will move up until the entire needle is covered by the needle guard.



- *The needle will not retract unless all the liquid is injected.*
- Speak to your doctor, pharmacist, or nurse if you think you have not given a full dose.
- A small amount of liquid or slight bleeding at the injection site is normal.
- Press a cotton ball or gauze pad on the injection site, **do not** rub.

Dispose

How to dispose of your Prefilled Syringe

Put your used Prefilled Syringe in a FDA-cleared sharps disposal container right away after use.



Do not throw away (dispose of) the Prefilled Syringe in the household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- made of a 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.

The Needle Cover, alcohol swab, cotton ball or gauze pad, and packaging may be placed in your household trash.

When your sharps disposal container is full, follow your community guidelines for the right way to dispose of your sharps disposal container, as there may be state or local laws about how you should throw away used Prefilled Syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: www.fda.gov/safesharpsdisposal

Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this.



WANT TO LEARN MORE ABOUT SIMLANDI?

Scan to learn more at SIMLANDI.com

Continued Important Safety Information for SIMLANDI® (adalimumab-ryvk) injection, for subcutaneous use

What should I tell my doctor BEFORE starting SIMLANDI?

Tell your doctor about all of your health conditions, including if you:

- Have an infection, are being treated for infection, or have symptoms of an infection.
- Get a lot of infections or have infections that keep coming back.
- Have diabetes.
- Have TB or have been in close contact with someone with TB, or were born in, lived in, or traveled where there is more risk for getting TB.
- Live or have lived in an area (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections, such as histoplasmosis, coccidioidomycosis, or blastomycosis. These infections may happen or become more severe if you use SIMLANDI. Ask your doctor if you are unsure you have lived in an area where these infections are common.
- Have or have had hepatitis B.
- Are scheduled for major surgery.
- Have or have had cancer.
- Have numbness or tingling or a nervous system disease such as multiple sclerosis or Guillain-Barré syndrome.
- Have or had heart failure.
- Have recently received or are scheduled to receive a vaccine. SIMLANDI patients may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting SIMLANDI.
- Are allergic to any SIMLANDI ingredients.
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed.
- Have a baby and you were using SIMLANDI during your pregnancy. Tell your baby's doctor before your baby receives any vaccines.

Also tell your doctor about all the medicines you take.

You should not take SIMLANDI with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

What should I watch for AFTER starting SIMLANDI?

SIMLANDI can cause serious side effects, including:

- **Serious infections.** These include TB and infections caused by viruses, fungi, or bacteria. Symptoms related to TB include a cough, low-grade fever, weight loss, or loss of body fat and muscle.
- **Hepatitis B infection in carriers of the virus.** Symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.
- **Allergic reactions.** Symptoms of a serious allergic reaction include hives; trouble breathing; and swelling of your face, eyes, lips, or mouth.
- **Nervous system problems.** Signs and symptoms include numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems (decreased blood cells that help fight infections or stop bleeding).** Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **Heart failure (new or worsening).** Symptoms include shortness of breath, swelling of your ankles or feet, and sudden weight gain.
- **Immune reactions, including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or rash on your cheeks or arms that gets worse in the sun.
- **Liver problems.** Symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of your stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis (new or worsening).** Symptoms include red scaly patches or raised bumps that are filled with pus.

Call your doctor or get medical care right away if you develop any of the above symptoms.

The most common side effects of SIMLANDI include injection site reactions (pain, redness, rash, swelling, itching, or bruising), upper respiratory infections (sinus infections), headaches, and rash. These are not all the possible side effects with SIMLANDI. Tell your doctor if you have any side effect that bothers you or that does not go away.

Remember, tell your doctor right away if you have an infection or symptoms of an infection, including:

- Fever, sweats, or chills
- Muscle aches
- Cough
- Shortness of breath
- Blood in phlegm
- Warm, red, or painful skin or sores on your body
- Diarrhea or stomach pain
- Burning when you urinate
- Urinating more often than normal
- Feeling very tired
- Weight loss

These are not all the possible side effects of SIMLANDI. For more information, speak with your doctor or pharmacist.

INDICATIONS

What is SIMLANDI?

SIMLANDI is a medicine called a tumor necrosis factor (TNF) blocker.

SIMLANDI is given by injection under the skin. SIMLANDI is used to reduce the signs and symptoms of:

- **moderate to severe rheumatoid arthritis (RA) in adults.** SIMLANDI can be used alone, with methotrexate, or with certain other medicines.
- **moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children 2 years of age and older.** SIMLANDI can be used alone or with methotrexate.
- **psoriatic arthritis (PsA) in adults.** SIMLANDI can be used alone or with certain other medicines.
- **ankylosing spondylitis (AS) in adults.**
- **moderate to severe hidradenitis suppurativa (HS) in adults.**
- **to treat moderate to severe Crohn's disease (CD) in adults and children 6 years of age and older.**
- **to treat moderate to severe ulcerative colitis (UC) in adults.** It is not known if adalimumab products are effective in people who stopped responding to or could not tolerate anti-TNF medicines.
- **to treat moderate to severe chronic plaque psoriasis (Ps) in adults** who have the condition in many areas of their body and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- **to treat non-infectious intermediate, posterior, and panuveitis in adults.**

If you have any questions about this information, be sure to discuss them with your healthcare provider.

To report **SUSPECTED ADVERSE REACTIONS**, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please read the [Full Prescribing Information](#), including [BOXED WARNINGS](#) and [Medication Guide](#).