

# AS CLOSE TO THE ORIGINAL AS IT GETS

 **Simlandi**  
(adalimumab-ryvk)  
Injection • 40mg/0.4mL

- ✓ FDA-APPROVED BIOSIMILAR  
INTERCHANGEABLE WITH HUMIRA®
- ✓ CUSTOM-DESIGNED  
AUTOINJECTOR
- ✓ SAVINGS PROGRAM



The SIMLANDI Autoinjector has been approved for the Arthritis Foundation's Ease of Use Certification, which recognizes products that have been tested and proven to make daily tasks easier.



## IMPORTANT SAFETY INFORMATION

### 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.

Please read Important Safety Information throughout and the full Prescribing Information, including **BOXED WARNINGS** and Medication Guide.



## WHAT IS SIMLANDI®?

**SIMLANDI is the first FDA-approved biosimilar medication interchangeable with the most prescribed version of Humira®\***

- To be approved as an interchangeable biosimilar, SIMLANDI underwent additional testing to show that patients like you can be switched between Humira and SIMLANDI without compromising treatment results

\*The most prescribed formulation of Humira is high concentration and citrate free.

**SIMLANDI is proven to have *no clinically meaningful differences* in safety or effectiveness with Humira**



As an interchangeable biosimilar,  
SIMLANDI works the same way as Humira

### IMPORTANT SAFETY INFORMATION

**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.

# WHAT DOES SIMLANDI<sup>®</sup> DO?

## SIMLANDI is a prescription medicine 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. SIMLANDI may prevent further damage to your bones and joints and may help your ability to perform daily activities
  - **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children 2 years 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. SIMLANDI may prevent further damage to your bones and joints and may help your ability to perform daily activities
  - **Ankylosing spondylitis (AS) in adults**
- To treat moderate to severe hidradenitis suppurativa (HS) in people 12 years and older
- 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
- 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 noninfectious intermediate, posterior, and panuveitis in adults and children 2 years of age and older

**SIMLANDI can be substituted for Humira<sup>®</sup>,\*  
whether you're new to therapy  
or currently taking Humira**

\*For any of the indications listed above.

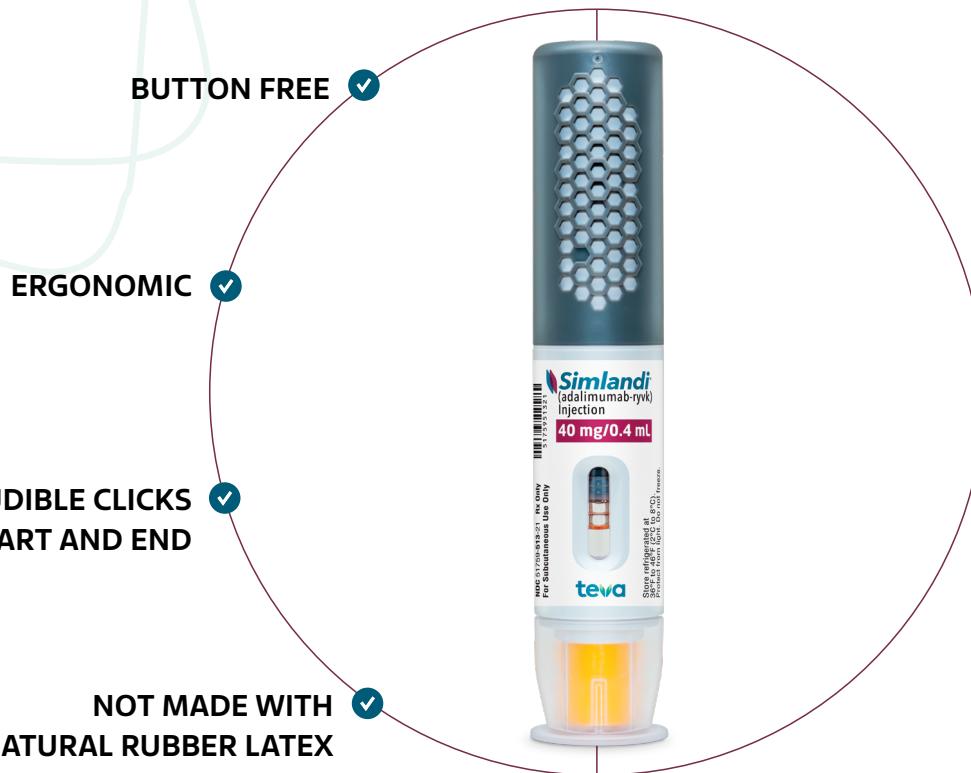
## IMPORTANT SAFETY INFORMATION

### What should I tell my doctor BEFORE starting SIMLANDI? (cont'd)

- 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.



# THE SIMLANDI® AUTOINJECTOR: ARTFULLY DESIGNED WITH YOU IN MIND



The SIMLANDI Autoinjector has been approved for the Arthritis Foundation's Ease of Use Certification, which recognizes products that have been tested and proven to make daily tasks easier.

SIMLANDI prefilled syringes are also available.

## IMPORTANT SAFETY INFORMATION

### What should I tell my doctor BEFORE starting SIMLANDI? (cont'd)

- 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.

## In a real-life patient handling study

The SIMLANDI<sup>®</sup> Autoinjector was evaluated by 107 patients with moderate to severe rheumatoid arthritis. Patients had no previous autoinjector experience.



## IMPORTANT SAFETY INFORMATION

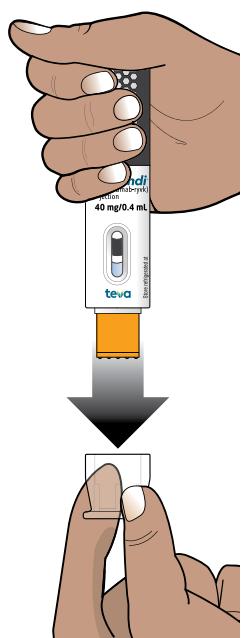
### What should I tell my doctor BEFORE starting SIMLANDI? (cont'd)

- 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<sup>®</sup> (abatacept), KINERET<sup>®</sup> (anakinra), REMICADE<sup>®</sup> (infliximab), ENBREL<sup>®</sup> (etanercept), CIMZIA<sup>®</sup> (certolizumab pegol), or SIMPONI<sup>®</sup> (golimumab). Tell your doctor if you have ever used RITUXAN<sup>®</sup> (rituximab), IMURAN<sup>®</sup> (azathioprine), or PURINETHOL<sup>®</sup> (mercaptopurine, 6-MP).

# SIMLANDI® AUTOINJECTOR INJECTION BASICS

## STEP 1



### Step 1: Remove the clear cap

Pull the clear cap straight off and throw it away. It is normal to see a few drops of liquid come out of the needle. Do not put the clear cap back on the autoinjector, since this may damage the needle. Once you've removed the clear cap, turn the autoinjector so that the orange needle sleeve points toward the injection site.

Please read the full Instructions for Use in the  
Prescribing Information before administering SIMLANDI

SIMLANDI prefilled syringes are also available.  
Talk to your doctor about how you should administer SIMLANDI.

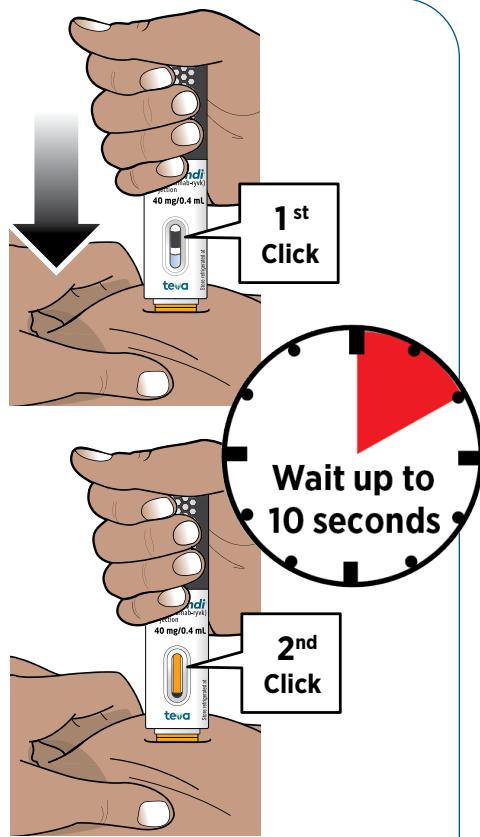
## IMPORTANT SAFETY INFORMATION

### 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.

## STEP 2



**Step 2: Firmly push the SIMLANDI® Autoinjector all the way down against the injection site at a 90° angle and keep pushing down during the injection**

The first “click” will signal the start of the injection. It may take up to 10 seconds after the first “click” to complete the injection. The injection is complete when the orange indicator has stopped moving and you hear a second “click.”

Do not lift up or let go of the pressure from the injection site until you have confirmed the injection is complete.

## Storing SIMLANDI

- Do not use after expiration date on the container
- Must be refrigerated at 36°F to 46°F (2°C to 8°C)
- DO NOT FREEZE. Do not use if frozen even if it has been thawed
- Store in original carton until time of administration to protect from light
- If needed (for example, when traveling), it may be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 30 days
  - Discard if not used within the 30-day period

## IMPORTANT SAFETY INFORMATION

### What should I watch for AFTER starting SIMLANDI? (cont'd)

- **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.

# YOU CAN SAVE WITH SIMLANDI®

Eligible patients may pay as little as \$0 for SIMLANDI



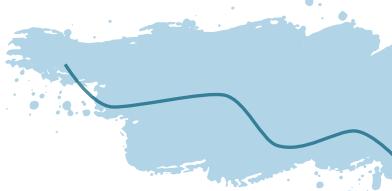
## SIMLANDI Savings Program

Enroll in the SIMLANDI Savings Program to receive cost support and pay as little as \$0 for your medicine.

### Eligibility requirements

- Offer is available for patients with commercial insurance only
- Offer is NOT available for patients eligible for Medicare, Medicaid, or any other form of government insurance coverage

For more information on the SIMLANDI Savings Program, go to [SIMLANDI.com/savings-program](http://SIMLANDI.com/savings-program)



## IMPORTANT SAFETY INFORMATION

### What should I watch for AFTER starting SIMLANDI? (cont'd)

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

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## IMPORTANT SAFETY INFORMATION

### What should I watch for AFTER starting SIMLANDI? (cont'd)

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

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](http://www.fda.gov/medwatch).

Please read Important Safety Information throughout and the full [Prescribing Information](#), including BOXED WARNINGS and Medication Guide.

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**teva** Biosimilars