



RENFLEXIS is FDA approved to treat the same health conditions as *Remicade*® (infliximab).

Important Safety Information

RENFLEXIS can lower your ability to fight infections. Serious and sometimes fatal events have occurred. Possible serious side effects may include infections, lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, or other cancers. To learn more about these and other serious risks, please read the Important Safety Information on pages 5–6 and the accompanying Medication Guide, and talk with your doctor. The physician Prescribing Information also is available.

RENFLEXIS®
(infliximab-abda) for injection,
for intravenous use 100 mg

RENFLEXIS is a prescription medication that is approved by the FDA to treat these health conditions:

Crohn's Disease

Can reduce signs and symptoms and induce and maintain remission in adult patients with moderately to severely active Crohn's disease who haven't responded well to other therapies

Pediatric Crohn's Disease

Can reduce signs and symptoms and induce and maintain remission in children (ages 6–17) with moderately to severely active Crohn's disease who haven't responded well to other therapies

Ulcerative Colitis

Can reduce signs and symptoms, induce and maintain remission, promote intestinal healing, and reduce or stop the need for steroids in adult patients with moderately to severely active ulcerative colitis who haven't responded well to other therapies

Pediatric Ulcerative Colitis

Can reduce signs and symptoms and induce and maintain remission in children (ages 6–17) with moderately to severely active ulcerative colitis who haven't responded well to other therapies

Rheumatoid Arthritis

Can reduce signs and symptoms, help stop further joint damage, and improve physical function in patients with moderately to severely active rheumatoid arthritis, in combination with methotrexate

Psoriatic Arthritis

Can reduce signs and symptoms of active arthritis, help stop further joint damage, and improve physical function in patients with psoriatic arthritis

Ankylosing Spondylitis

Can reduce signs and symptoms in patients with active ankylosing spondylitis

Plaque Psoriasis

Approved for the treatment of adult patients with chronic (doesn't go away) severe (extensive and/or disabling) plaque psoriasis under the care of a physician who will determine if RENFLEXIS is appropriate considering other available therapies

Talk with your doctor to see if RENFLEXIS is right for you or visit renflexis.com to learn more.

Important Safety Information about RENFLEXIS can be found on pages 5 and 6.

Please read the accompanying Medication Guide for RENFLEXIS, including the information about serious infections and cancers, and discuss it with your doctor. The physician Prescribing Information is also available.



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Getting started on RENFLEXIS.

Living with an autoimmune disease can have its challenges. Your doctor may be discussing treatment options with you, which may include starting or transitioning to a medicine called RENFLEXIS.

What is RENFLEXIS?

RENFLEXIS is a prescription medicine that treats the same health conditions as *Remicade*[®] (infliximab). RENFLEXIS is a biosimilar, which is a type of biologic medicine. Biosimilars are approved by the Food and Drug Administration (FDA) as being highly similar to an already approved biologic medicine. For example, RENFLEXIS is biosimilar to the already approved biologic medicine *Remicade*, also known as the reference biologic product.

No clinically meaningful differences in effectiveness and safety

RENFLEXIS has undergone rigorous testing to show the FDA that compared to *Remicade*, it has no clinically meaningful differences in effectiveness and safety.

RENFLEXIS works the same way as *Remicade*

RENFLEXIS works in the body in the same way as *Remicade*. It has the same dosage, and it's taken the same way.

The role of biosimilars like RENFLEXIS.

Biosimilars offer doctors and patients more treatment options, and that may create more competition.

Biosimilars, like RENFLEXIS, may help more people get access to certain medicines. They may also help reduce costs in the health care system.

To learn more, visit renflexis.com

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If you're transitioning to RENFLEXIS, your treatment routine will be the same as *Remicade*[®] (infliximab).

Your doctor may be talking with you about transitioning to RENFLEXIS from *Remicade*. If you and your doctor decide that RENFLEXIS is right for you, here's some information that you may find helpful to know.

SAME ROUTINE

You will be given RENFLEXIS on the same schedule as *Remicade*. If you've already completed the starting doses for *Remicade*, you do not need the starting doses for RENFLEXIS.

SAME DOSAGE

RENFLEXIS has the same dosing as *Remicade*. Your dose of RENFLEXIS will be customized to your weight.

SAME WAY

A nurse will give you RENFLEXIS the same way as *Remicade*. You'll be given an intravenous (IV) infusion over a period of about 2 hours. IV infusion means a needle will be placed in a vein—most likely in your arm.

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Important Safety Information

Only your doctor can recommend a course of treatment after checking your health condition. RENFLEXIS can cause serious side effects such as lowering your ability to fight infections. **Some patients, especially those 65 years and older, have had serious infections caused by viruses, fungi, or bacteria that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with RENFLEXIS.**

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking infliximab products and azathioprine or 6-mercaptopurine.

For children and adults taking TNF blockers, including RENFLEXIS, the chances of getting lymphoma or other cancers may increase.

You should discuss any concerns about your health and medical care with your doctor.

What should I tell my doctor before I take RENFLEXIS?

You should let your doctor know if you have or ever had any of the following:

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start RENFLEXIS. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with, and during treatment with, RENFLEXIS. Even if your TB test is negative, your doctor should carefully monitor you for TB infections while you are taking RENFLEXIS. Patients who had a negative TB skin test before receiving infliximab products have developed active TB.
- Lived in a region where certain fungal infections like histoplasmosis, coccidioidomycosis, cryptococcosis, or blastomycosis are common.

These infections may develop or become more severe if you take RENFLEXIS. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, cryptococcosis, or blastomycosis is common, ask your doctor.

- Infections that keep coming back, diabetes, or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take RENFLEXIS.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV. Your doctor will test you for HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barré syndrome).

Also tell your doctor if you:

- Use the medicines *Kineret*[®] (anakinra), *Orencia*[®] (abatacept), or *Actemra*[®] (tocilizumab) or other medicines called biologics used to treat the same problems as RENFLEXIS.
- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using RENFLEXIS during your pregnancy. Tell your baby's doctor about your RENFLEXIS use. If your baby receives a live vaccine within 6 months after birth, your baby may develop infections with serious complications that can lead to death.

(Continued on page 6)

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Important Safety Information

(continued from page 5)

- Recently received or are scheduled to receive a vaccine. Adults and children taking RENFLEXIS should not receive live vaccines or treatment with a weakened bacteria (such as Bacille Calmette-Guérin [BCG] for bladder cancer) while taking RENFLEXIS.

What should I watch for and talk to my doctor about before or while taking RENFLEXIS?

The following serious (sometimes fatal) side effects have been reported in people taking RENFLEXIS. You should tell your doctor right away if you have any of the signs listed below:

- Infections (like TB, blood infections, pneumonia)—fever, tiredness, cough, flu, or warm, red, or painful skin or any open sores. RENFLEXIS can make you more likely to get an infection or make any infection that you have worse.
- Lymphoma, or any other cancers in adults and children.
- Skin Cancer—any changes in or growths on your skin.
- Cervical Cancer—your doctor may recommend that you be regularly screened. Some women with rheumatoid arthritis, particularly those over 60, have developed cervical cancer.
- Heart Failure—new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash, and/or joint pain.
- Other heart problems within 24 hours of infusion, including heart attack, low blood flow to the heart, or abnormal heart rhythm—chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, and/or a fast or a slow heartbeat.
- Liver Injury—jaundice (yellow skin and eyes), dark brown urine, right-sided abdominal pain, fever, or severe tiredness.
- Blood Problems—in some patients taking infliximab products, the body may not make enough of the blood cells that help fight infections or help stop


bleeding. Tell your doctor if you have a fever that does not go away, bruising, bleeding, or severe paleness.

- Nervous System Disorders—numbness, weakness, tingling, changes in your vision, or seizures.
- Stroke within 24 hours of infusion—numbness or weakness of the face, arm, or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking; dizziness; loss of balance or coordination; or a sudden, severe headache.
- Allergic Reactions (some severe) during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, and fever or chills.
- Delayed Allergic Reactions (3 to 12 days after infusion)—fever, rash, headache, sore throat, muscle or joint pain, swelling of the face and hands, or difficulty swallowing.
- Lupus-like Syndrome—chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun.
- Psoriasis—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

The more common side effects with infliximab products are respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing, and stomach pain.

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A woman in a green sleeveless dress and white pants is walking a beagle dog on a leash in a park. The background shows trees and a bench.

Your dose of RENFLEXIS is personalized for you based on your weight.

A health care professional will give you RENFLEXIS as an IV infusion. This means a needle will be placed in a vein—most likely in your arm. Your doctor will customize your dose based on your weight.

Over **THE FIRST 6 WEEKS** you'll receive **3 STARTING DOSES** of RENFLEXIS

Then you may only need treatment **ONCE EVERY 6 TO 8 WEEKS**

Some patients who have not responded well with rheumatoid arthritis may need treatment every 4 weeks.

For tips on how to prepare for an infusion, visit renflexis.com and talk to your doctor.

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Discussing RENFLEXIS with your doctor.

If you're talking with your doctor about RENFLEXIS, it's good to know the following key points:

No clinically meaningful differences in effectiveness and safety

RENFLEXIS has been through rigorous testing to show the FDA that it is highly similar in effectiveness and safety to *Remicade*® (infliximab).

Treats the same health conditions

RENFLEXIS is approved by the FDA to treat the same health conditions as *Remicade*.

Taken the same way

RENFLEXIS is given the same way as *Remicade*—as an IV infusion, which is given by a nurse.

Works the same way

RENFLEXIS works in the body in the same way as *Remicade*.

Making the transition to RENFLEXIS.

The information in this brochure addresses questions that may come to mind when making the transition from *Remicade* to RENFLEXIS. If you have additional questions, be sure to speak with your doctor.

Working together, your doctor can explain how you can expect the same treatment routine with RENFLEXIS as you've had with *Remicade*. You'll have the same dosage and the medication will be given the same way.

RENFLEXIS is not right for everyone and individual results may vary. Once again, talk with your doctor about any questions you may have about RENFLEXIS.

Visit renflexis.com to learn more.

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Get support from the start with The Organon Access Program.

Get answers to questions about insurance, co-pay assistance for eligible, privately insured patients, and more. With The Organon Access Program for RENFLEXIS, you can:



Speak with a live representative
by calling 866-847-3539
(M–F, 8 AM to 8 PM Eastern Time)



Find out about insurance coverage
for RENFLEXIS, including any
out-of-pocket costs



Learn about options for
co-pay assistance for eligible,
privately insured patients

To learn more about The Organon Access Program, visit [renflexis.com](https://www.renflexis.com) or call 866-847-3539.

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