Treatment with RENFLEXIS

ORGANON

Answers to questions you may have

You may be having conversations with your doctor about switching from *Remicade*® (infliximab) to a biosimilar medicine called RENFLEXIS. The following information may be helpful to you during your transition.

What are biosimilars?

Biosimilars are prescription medicines that have been approved by the Food and Drug Administration (FDA) as being highly similar to an already approved biologic medicine. The already approved biologic medicine is known as the reference product or originator biologic product.

Biosimilars are tested to prove that they are similar to the originator biologic products in terms of effectiveness and safety.

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 4–5 and the Medication Guide, and talk with your doctor. The physician Prescribing Information also is available.

Will my treatment routine stay the same?

Yes, your treatment routine stays the same with RENFLEXIS. The medicine is given the same way as the originator biologic product. A health care professional will give you RENFLEXIS as an intravenous (IV) infusion. This means a needle will be placed in a vein—most likely in your arm.

You'll have the same treatment schedule with RENFLEXIS and your infusion will take about the same amount of time. As with any prescription medicine, your doctor will determine the right dose of RENFLEXIS for you.

Biosimilars like RENFLEXIS are approved under a law called the Biologics Price Competition and Innovation Act. One of the goals of this act is to help more people get access to certain medicines.

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

How is a biosimilar approved by the FDA?

A biosimilar must show that it has no clinically meaningful differences in effectiveness and safety from the originator biologic product. To demonstrate this, the FDA requires a biosimilar to be tested to prove the medicine is similar in several ways, including:

Similar effectiveness and safety
A biosimilar has to prove that it is highly similar in effectiveness and safety.

Same in how it works
A biosimilar works in the body in the same way to the originator biologic product.

Similar structure
A biosimilar is developed in a way that ensures that the active substance is similar in structure to the originator biologic product.

Is there educational support available for patients taking RENFLEXIS?

Patients taking RENFLEXIS have access to educational materials. Go to **www.renflexis.com/patient-education/** to see all of the resources available to you, including:

- Informative brochure about RENFLEXIS.
- Tips to help you manage your condition.
- A guide with questions to ask your doctor.
- A video that explains what to expect with an infusion.

Is financial support available for patients taking RENFLEXIS?

The Organon Access Program for RENFLEXIS may be able to help answer your questions about insurance, co-pay assistance for eligible, privately-insured patients, and more. You can:

Speak to a live Organon Access Program representative by calling **866-847-3539**.

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

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

To learn more about The Organon Access Program, visit **www.renflexis.com** or call **866-847-3539**.

Watch a video on how to prepare for your infusion.

IMPORTANT SAFETY INFORMATION about RENFLEXIS can be found on pages 4 and 5.

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

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RENFLEXIS is an FDA-approved prescription medicine used 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

To learn more about RENFLEXIS, download the RENFLEXIS educational brochure

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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.
- 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.

(Continued on page 5)

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IMPORTANT SAFETY INFORMATION *(Continued from page 4)*

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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If you have any questions, visit **www.renflexis.com** or talk with your doctor.

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