A Guide for Patients New to Therapy or Switching to INFLECTRA

SELECTED SAFETY INFORMATION

Only your doctor can recommend a course of treatment after checking your health condition. INFLECTRA® (infliximab-dyyb) 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 INFLECTRA®.

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 INFLECTRA®, the chances of getting lymphoma or other cancers may increase.

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

INFLECTRA® is a trademark of Hospira UK, a Pfizer company.

Please see additional Important Safety Information throughout, Indications on page 5, and full Prescribing Information, including BOXED WARNING and Medication Guide, available at InflectraHCP.com.
INFLECTRA is the first biosimilar to Remicade® (infliximab). Both INFLECTRA and Remicade are infliximab products.

The US Food and Drug Administration (FDA) approved INFLECTRA to treat the same conditions* as Remicade:
- Rheumatoid Arthritis—adults with moderately to severely active rheumatoid arthritis, along with the medicine methotrexate
- Crohn’s Disease—children 6 years and older and adults with Crohn’s disease who have not responded well to other medicines
- Ankylosing Spondylitis
- Psoriatic Arthritis
- Plaque Psoriasis—adult patients with plaque psoriasis that is chronic (doesn’t go away), severe, extensive, and/or disabling
- Ulcerative Colitis—adults with moderately to severely active ulcerative colitis who have not responded well to other medicines

For full Indications, please see page 5.

*INFLECTRA is not currently approved for pediatric ulcerative colitis.

What is INFLECTRA?

In studies, INFLECTRA showed no clinically meaningful differences from Remicade.

This means that INFLECTRA is expected to work in the same way as Remicade. You or your doctor may consider treatment with INFLECTRA if you are new to infliximab therapy, or if you are currently taking Remicade.

Remicade is a registered trademark of Janssen Biotech, Inc.

What is a biosimilar medicine?

A biosimilar is exactly what it sounds like: a highly similar version of a biologic medicine or “biologic.” A biologic is a special type of medicine that’s created from living cells.

- Biologics help treat or prevent a variety of conditions
- Biosimilars are not generic drugs. They are not exact copies since they are made from living cells. They are highly similar versions of biologics
- Biosimilars must, however, be proven to work in the same way as the biologic product to which they are compared, also known as the reference product

Biosimilars must meet strict standards established by the FDA. INFLECTRA was proven to:
- Have a similar safety profile as Remicade
- Be an effective therapy
- Work in the same way as Remicade

In 3 separate clinical studies, INFLECTRA showed similarity to Remicade in rheumatoid arthritis (RA), ankylosing spondylitis (AS), and Crohn’s disease (CD).* Because INFLECTRA was approved as a biosimilar, INFLECTRA can be expected to work similarly to Remicade in all other eligible indications as well.

*This study was not used in the FDA approval process.

How is INFLECTRA similar to Remicade?

SELECTED SAFETY INFORMATION

What should I tell my doctor before I take INFLECTRA®?

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 INFLECTRA®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- 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. (Continued on next column)

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How long have biosimilars and INFLECTRA been available?

Biosimilar medicines have been available outside of the United States for more than 10 years, and have been shown to be as effective as other biological medicines.*

- INFLECTRA has over 170,000 patient-years of experience outside the US*
- It has been available in the US since 2016 and outside the US since 2012*

How do I receive treatment with INFLECTRA?

After your doctor prescribes INFLECTRA, treatment begins the same way it would with Remicade® (infliximab):

1 INFLECTRA is given by infusion, usually in a doctor’s office, hospital, or infusion center
2 An initial dosing phase is delivered by your doctor or an infusion specialist
3 INFLECTRA is infused via an IV needle in the arm
4 The average infusion time is about 2 hours

*INFLECTRA is marketed under other brand names in some countries.

What should I consider if I’m switching to INFLECTRA from Remicade?

Your doctor may decide to switch you from Remicade to INFLECTRA, a potentially lower cost option. Because INFLECTRA is a biosimilar to Remicade, you can expect the same treatment experience that you had with Remicade.

Remember that INFLECTRA:

- Is approved for all eligible indications of Remicade
- Has a similar efficacy and safety profile to Remicade
- Is dosed the same way as Remicade
- Is delivered the same way as Remicade

If you’re switching to INFLECTRA, your dosage typically won’t change. Your doctor will determine the right dose of INFLECTRA based on your body weight, and how often you should receive it.

In addition, depending on your insurance plan, you may be able to save with a prescription for INFLECTRA.

SELECTED SAFETY INFORMATION

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 INFLECTRA®.

- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using INFLECTRA® during your pregnancy. Tell your baby’s doctor about your INFLECTRA® 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 next column)

SELECTED SAFETY INFORMATION

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

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

The following serious (sometimes fatal) side effects have been reported in people taking infliximab products.

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. INFLECTRA® can make you more likely to get an infection or make any infection that you have worse. (Continued on page 4)
INFLECTRA has broad coverage that varies by state. INFLECTRA is covered by Medicare Part B and most Medicaid plans, depending on the state. INFLECTRA also is covered by various insurance plans provided by employers.

You or your doctor should check your healthcare coverage prior to being treated with INFLECTRA. The Pfizer enCompass™ program can help assess your coverage for INFLECTRA.

Will my insurance cover INFLECTRA?

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Questions about starting on or switching to INFLECTRA?

Download the Doctor Discussion Guide, available on the INFLECTRA website at www.pfizerinflectra.com for a helpful list of questions to ask your doctor, and information on our patient support program, Pfizer enCompass™.

Terms and Conditions

With this program, eligible patients may be responsible for $0 co-pay per eligible INFLECTRA treatment, subject to a maximum benefit of $20,000 per calendar year for out-of-pocket expenses for INFLECTRA including co-pays or coinsurances. The amount of any benefit is the difference between your co-pay and $0. After the maximum of $20,000 you will be responsible for the remaining monthly out-of-pocket costs. No claim for reimbursement of the out-of-pocket expense amount covered by this program shall be submitted to any third-party payer, whether public or private. This offer is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plans or other health or pharmacy benefit programs. This offer cannot be combined with any other rebate/coupon, free trial or similar offer for the specified prescription. This offer is limited to 1 per person during this offering period and is not transferable. Offer good only in the United States and Puerto Rico. Certain restrictions may apply. Offer may not be available to patients in all states. Offer may not be available to patients in all states. Offer may not be available to patients in all states. Offering period:

Pfizer enCompass™ Program

Pfizer enCompass™ Program offers a variety of patient support programs to help patients access INFLECTRA therapy, including assistance for eligible uninsured and insured patients who cannot afford their out-of-pocket costs. A team of trained Access Counselors is available to help you understand your insurance benefits and to work with your healthcare provider and health insurer on your behalf to help access treatment with INFLECTRA. To assess your coverage for INFLECTRA or your patient support needs, please contact an Access Counselor at 1-844-722-6672, Monday–Friday, 9 AM to 8 PM ET.

Patients now may pay $0 per INFLECTRA treatment for claims received by the program as of April 1, 2018

| Eligible patients can receive assistance up to $20,000 per calendar year* |

*The co-pay program covers only drug costs, not procedures, administration fees, or office visits. Please see full Terms and Conditions below.

Terms and Conditions

The Pfizer enCompass Co-Pay Assistance Program for INFLECTRA is not valid for prescriptions that are eligible to be reimbursed in whole or in part, by Medicaid, Medicare, Tricare or other federal or state healthcare programs (including any state prescription drug assistance programs) and the Government Health Insurance Plan available in Puerto Rico (formerly known as “La Reforma de Salud”). This program is not health insurance. No membership fees required.

SELECTED SAFETY INFORMATION

You should tell your doctor right away if you have any of the signs listed below: (continued)

• Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash, and/or joint pain.
• 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.
• 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.

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IMPORTANT SAFETY INFORMATION AND INDICATIONS

Only your doctor can recommend a course of treatment after checking your health condition. INFLECTRA® (infliximab-dyyb) 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 INFLECTRA®.

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What should I tell my doctor before I take INFLECTRA®?

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 INFLECTRA®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- 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 INFLECTRA®.
- 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-Barre 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 INFLECTRA®.
  - Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using INFLECTRA® during your pregnancy. Tell your baby’s physician who will determine if INFLECTRA® is appropriate considering your pregnancy.
  - Haven’t responded well to other therapies
  - Haven’t responded well to other therapies

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

The following serious (sometimes fatal) side effects have been reported in people taking infliximab products:

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. INFLECTRA® can make you more likely to get an infection or make any infection that you have worse.
- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash, and/or joint pain.
- 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.
- 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 disorders—fever that doesn’t go away, bruising, bleeding, or severe paleness.
- Nervous system disorders—numbness, weakness, bruising, bleeding, or severe paleness.
- 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 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, or 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 include:

- Respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing, and stomach pain.

INDICATIONS

INFLECTRA® is a prescription medication used to treat:

**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

**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

**Ankylosing Spondylitis**
- Can reduce signs and symptoms in patients with active ankylosing spondylitis

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

**Plaque Psoriasis**
- Approved for the treatment of adult patients with chronic severe (extensive and/or disabling) plaque psoriasis under the care of a physician who will determine if INFLECTRA® is appropriate considering other available therapies
Reference:

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