



Infliximab: An Unbranded Biologic Option From Janssen

SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with REMICADE® and Infliximab. Infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens (eg, TB, histoplasmosis) have been reported. Lymphoma, including cases of fatal hepatosplenic T-cell lymphoma (HSTCL), and other malignancies have been reported, including in children and young adult patients. Due to the risk of HSTCL, mostly reported in Crohn's disease and ulcerative colitis, assess the risk/benefit, especially if the patient is male and is receiving azathioprine or 6-mercaptopurine treatment. REMICADE® and Infliximab are contraindicated at doses >5 mg/kg in patients with moderate or severe heart failure and in patients with severe hypersensitivity reactions to REMICADE® and Infliximab. Other serious side effects reported include melanoma, Merkel cell carcinoma, invasive cervical cancer, hepatitis B reactivation, hepatotoxicity, hematological events, hypersensitivity, cardiovascular and cerebrovascular reactions during and after infusion, neurological events, and lupus-like syndrome. Please see related and other Important Safety Information on [pages 12-15](#) for REMICADE® and Infliximab.

INDICATIONS

Crohn's Disease

REMICADE® (infliximab) and Infliximab are indicated for:

- reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy.
- reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing CD.

Pediatric Crohn's Disease

REMICADE® and Infliximab are indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active CD who have had an inadequate response to conventional therapy.

Ulcerative Colitis

REMICADE® and Infliximab are indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis

REMICADE® and Infliximab are indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active UC who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis

REMICADE® or Infliximab, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA).

Ankylosing Spondylitis

REMICADE® and Infliximab are indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS).

Psoriatic Arthritis

REMICADE® and Infliximab are indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis (PsA).

Plaque Psoriasis

REMICADE® and Infliximab are indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis (Ps) who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. REMICADE® or Infliximab should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

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SELECTED IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with REMICADE[®] and Infliximab. Infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens (eg, TB, histoplasmosis) have been reported. Lymphoma, including cases of fatal hepatosplenic T-cell lymphoma (HSTCL), and other malignancies have been reported, including in children and young adult patients. Due to the risk of HSTCL, mostly reported in Crohn’s disease and ulcerative colitis, assess the risk/benefit, especially if the patient is male and is receiving azathioprine or 6-mercaptopurine treatment. REMICADE[®] and Infliximab are contraindicated at doses >5 mg/kg in patients with moderate or severe heart failure and in patients with severe hypersensitivity reactions to REMICADE[®] and Infliximab. Other serious side effects reported include melanoma, Merkel cell carcinoma, invasive cervical cancer, hepatitis B reactivation, hepatotoxicity, hematological events, hypersensitivity, cardiovascular and cerebrovascular reactions during and after infusion, neurological events, and lupus-like syndrome. Please see related and other Important Safety Information on [pages 12-15](#) for REMICADE[®] and Infliximab.

Infliximab: An Unbranded Biologic From Janssen

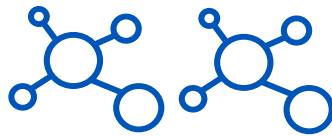
An unbranded biologic is NOT a biosimilar



Brand-Name Biologic¹

Approved based on a full complement of safety and effectiveness data

Produced through biotechnology in a living system (ie, a “cell line”)



Unbranded Biologic²

The **same product** as the brand-name biologic

Produced using the **same** cell line as the brand-name biologic



Biosimilar^{1,3}

Highly similar to brand-name biologic* with no clinically meaningful differences

Produced using a **different** cell line

*“Brand-name biologic” refers to the reference biologic.

An unbranded biologic is²:

An approved brand-name biologic being marketed under its approved biologics license[†] without the brand name

Considered by the FDA to be the **same product** as the brand-name biologic under the **same** biologics license[†]

The **same** in strength, dosage form, route of administration, and presentation as the brand-name biologic

[†]Biologics are FDA-approved through a biologics license application (BLA).

[‡]No difference in strength, dosage form and route of administration, and presentation vs its approved brand-name biologic.

FDA = US Food and Drug Administration.

Janssen's unbranded Infiximab is REMICADE® without the brand name⁴⁻⁶



Produced from the **same** cell line and at the **same** manufacturing sites as REMICADE®



Available in the **same** strength, **same** dosage form, and **same** route of administration as REMICADE®



Approved for all the **same** indications as REMICADE® with the **same** safety and efficacy profile



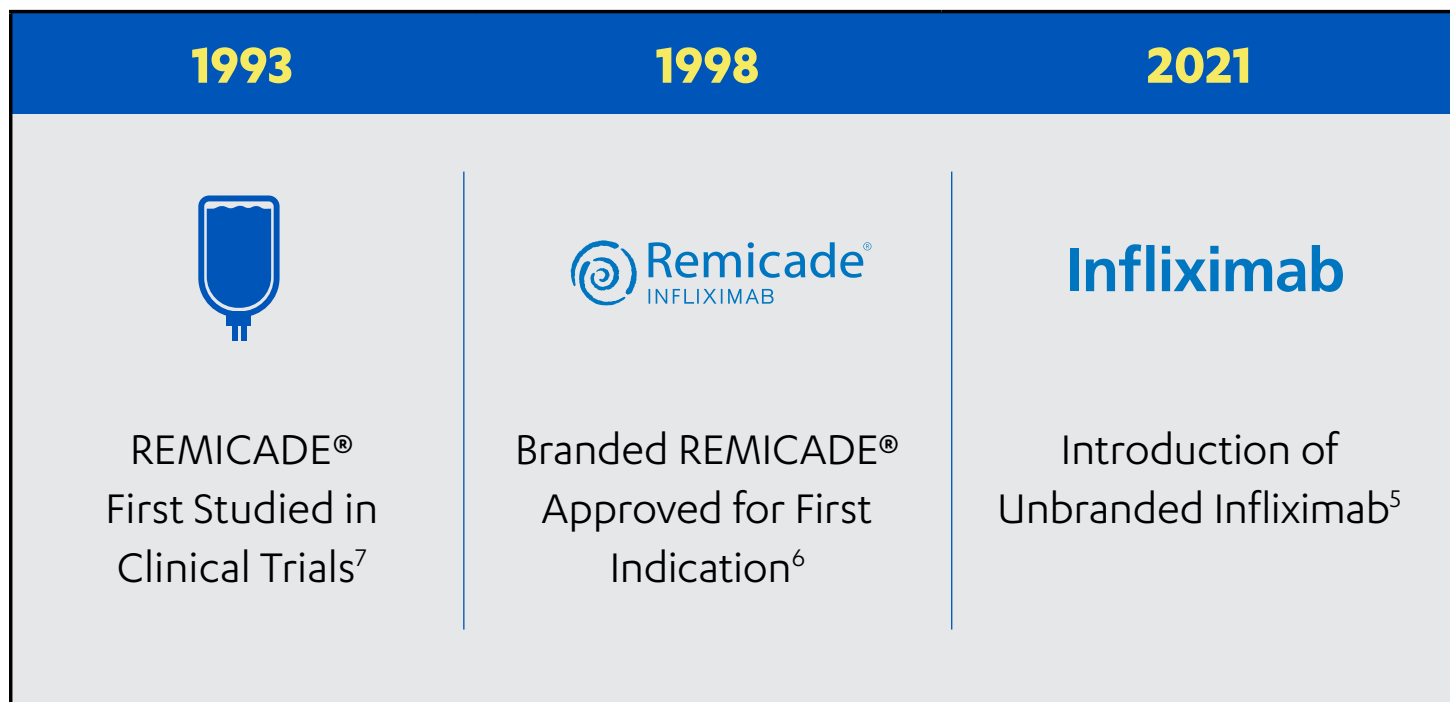
Offering the **same** affordability and patient support programs as REMICADE®

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Unbranded Infliximab Builds on the 20-Year Manufacturing Heritage of REMICADE® (infliximab)

Product timeline



**MORE THAN 3 MILLION PATIENTS WORLDWIDE
HAVE BEEN PRESCRIBED REMICADE®^{1*}**

*Cumulative exposure from August 1998 through August 2022 in all approved indications.¹

Product profile for Infiximab^{4,5}

Infiximab 100 mg per vial Single-dose vial for reconstitution and dilution	
NDC	57894-160-01
How Supplied	10 vials per unit (box)
WAC [†]	\$475 per vial



All information is as of June 2023.

[†]WAC is a published list price which does not contain any discounts, price concessions, or chargebacks extended to wholesalers or other end users. Wholesalers and distributors determine the actual sales price to end-user customers.

JANSSEN'S UNBRANDED Infiximab IS PRICED 59% LOWER THAN BRANDED REMICADE®, BASED ON WAC⁴

NDC = National Drug Code; WAC = Wholesale Acquisition Cost.

SELECTED IMPORTANT SAFETY INFORMATION

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Infliximab Dosing and Administration⁵

Dosing of Infliximab for adults

Infusions are administered every 8 weeks (or 6 weeks for those with active Ankylosing Spondylitis) after 3 induction doses.

Infliximab is infused by intravenous (IV) infusion over a period of not less than 2 hours.

Recommended Dosage and Intervals for Infliximab in Adult Patients

Indication	Induction	Maintenance
Moderately to Severely Active Crohn's Disease* <small>*Patients who do not respond by Week 14 are unlikely to respond with continued dosing, and consideration should be given to discontinuing Infliximab in these patients.</small>	5 mg/kg 0, 2, and 6 weeks	5 mg/kg [†] every 8 weeks <small>†For adult patients who respond and then lose their response, consideration may be given to treatment with 10 mg/kg every 8 weeks.</small>
Moderately to Severely Active Ulcerative Colitis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks
Moderately to Severely Active Rheumatoid Arthritis [‡] <small>‡In conjunction with methotrexate.</small>	3 mg/kg 0, 2, and 6 weeks	3 mg/kg [§] every 8 weeks <small>§For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks bearing in mind that risk of serious infections is increased at higher doses.</small>
Active Ankylosing Spondylitis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 6 weeks
Active Psoriatic Arthritis <small> Can be used with or without methotrexate.</small>	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks
Chronic Severe Plaque Psoriasis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks

Dosing of Infliximab for pediatric patients

Infusions are administered every 8 weeks after 3 induction doses. Infliximab is administered by IV infusion over a period of not less than 2 hours.

Recommended Dosage and Intervals for Infliximab in Pediatric Patients (≥6 Years)

Indication	Induction	Maintenance
Moderately to Severely Active Crohn's Disease	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks
Moderately to Severely Active Ulcerative Colitis	5 mg/kg 0, 2, and 6 weeks	5 mg/kg every 8 weeks

SELECTED IMPORTANT SAFETY INFORMATION

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Janssen CarePath Is Your One Source for Access, Affordability, and Treatment Support for Your Patients



Access support to help navigate payer processes

Janssen CarePath helps verify insurance coverage for your patients taking Infliximab and provides reimbursement information.

Online benefits investigation and prior authorization support at [JanssenCarePathPortal.com](https://www.janssencarepathportal.com)



Affordability support to help your patients start and stay on the treatment you prescribe

Janssen CarePath can help you find out what affordability assistance may be available for your patients taking Infliximab.

Comprehensive Provider Portal to enroll eligible patients in the Janssen CarePath Savings Program and more at [JanssenCarePathPortal.com](https://www.janssencarepathportal.com)



Treatment support to help your patients get informed and stay on Infliximab

Janssen CarePath provides additional support to your patients, including patient education, web-based resources, and personalized reminders.



If you have questions, call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728), Monday – Friday, 8:00 AM – 8:00 PM ET



Sign Up or Log In to the Provider Portal at [JanssenCarePathPortal.com](https://www.janssencarepathportal.com)



Visit [JanssenCarePath.com](https://www.janssencarepath.com)

Please see Important Safety Information for Infliximab and REMICADE® (infliximab) on [pages 12-15](#).

The Janssen CarePath Savings Program for REMICADE® and Infiximab



The Janssen CarePath Savings Program for REMICADE® now covers Infiximab.



Add Infiximab to the patient account from your patient dashboard on the Provider Portal.



Request a Benefits Investigation for Infiximab and follow the steps to initiate the BI process.

Eligible patients who have been prescribed Infiximab are automatically enrolled in the Janssen CarePath Savings Program for REMICADE® and Infiximab and can use their Savings Program card for program benefits for Infiximab.

The patient will NOT need to obtain a replacement card for the combined Savings Program.

All Savings Program details for REMICADE® are the same for Infiximab:

- Eligible patients will continue to pay **\$5 for each dose**, with a \$20,000 maximum program benefit per calendar year
- If the patient has used a portion of their maximum program benefit per calendar year for REMICADE®, the remaining amount can be used for Infiximab

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with either REMICADE® (infliximab) or Infliximab are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue either REMICADE® or Infliximab if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB.** Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before and during treatment with either REMICADE® or Infliximab.^{1,2} Treatment for latent infection should be initiated prior to treatment with either REMICADE® or Infliximab.
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, pneumocystosis, and cryptococcosis.** Patients may present with disseminated, rather than localized, disease. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella, Listeria, and Salmonella.**

The risks and benefits of treatment with either REMICADE® or Infliximab should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with either REMICADE® or Infliximab, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy, who are on treatment for latent TB, or who were previously treated for TB infection.

Risk of infection may be higher in patients greater than 65 years of age, pediatric patients, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. In clinical trials, other serious infections observed in patients treated with either REMICADE® or Infliximab included pneumonia, cellulitis, abscess, and skin ulceration.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including either REMICADE® or Infliximab. Approximately half of these cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including either REMICADE® or Infliximab. These cases have had a very aggressive disease course and have been fatal. The majority of reported REMICADE® and Infliximab cases have occurred in patients with Crohn's disease or ulcerative

colitis and most were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with either REMICADE® or Infliximab at or prior to diagnosis. Carefully assess the risks and benefits of treatment with either REMICADE® or Infliximab, especially in these patient types.

In clinical trials of all TNF blockers, more cases of lymphoma were observed compared with controls and the expected rate in the general population. However, patients with Crohn's disease, rheumatoid arthritis, or plaque psoriasis may be at higher risk for developing lymphoma. In clinical trials of some TNF blockers, including either REMICADE® or Infliximab, more cases of other malignancies were observed compared with controls. The rate of these malignancies among patients treated with either REMICADE® or Infliximab was similar to that expected in the general population whereas the rate in control patients was lower than expected. Cases of acute and chronic leukemia have been reported with postmarketing TNF-blocker use. As the potential role of TNF blockers in the development of malignancies is not known, caution should be exercised when considering treatment of patients with a current or a past history of malignancy or other risk factors such as chronic obstructive pulmonary disease (COPD).

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocker therapies, including either REMICADE® or Infliximab. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

A population-based retrospective cohort study found a 2- to 3-fold increase in the incidence of invasive cervical cancer in women with rheumatoid arthritis treated with either REMICADE® or Infliximab compared to biologics-naïve patients or the general population, particularly those over 60 years of age. A causal relationship between either REMICADE® or Infliximab and cervical cancer cannot be excluded. Periodic screening should continue in women treated with either REMICADE® or Infliximab.

CONTRAINDICATIONS

The use of either REMICADE® or Infliximab at doses >5 mg/kg is contraindicated in patients with moderate or severe heart failure. REMICADE® and Infliximab are contraindicated in patients with a previous severe hypersensitivity reaction to infliximab or any of the inactive ingredients of REMICADE® and Infliximab or any murine proteins (severe hypersensitivity reactions have included anaphylaxis, hypotension, and serum sickness).

HEPATITIS B REACTIVATION

TNF blockers, including REMICADE® and Infliximab, have been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases were fatal. Patients should be tested for HBV infection before initiating either REMICADE® or Infliximab. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing either REMICADE® or Infliximab for patients identified as carriers of HBV and monitor closely for active HBV infection during and following termination of therapy with either REMICADE® or Infliximab. Discontinue either REMICADE® or Infliximab in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of either REMICADE® or Infliximab and monitor patients closely.

Important Safety Information continued on the next page.

IMPORTANT SAFETY INFORMATION (cont'd)

HEPATOTOXICITY

Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported in patients receiving either REMICADE® (infliximab) or Infliximab postmarketing. Some cases were fatal or required liver transplant. Aminotransferase elevations were not noted prior to discovery of liver injury in many cases. Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or marked liver enzyme elevations (eg, ≥ 5 times the upper limit of normal) develop, either REMICADE® or Infliximab should be discontinued, and a thorough investigation of the abnormality should be undertaken.

HEART FAILURE

In a randomized, placebo-controlled study in patients with moderate or severe heart failure (NYHA Functional Class III/IV), higher mortality rates and a higher risk of hospitalization were observed at Week 28 at a dose of 10 mg/kg and higher rates of cardiovascular events were observed at both 5 mg/kg and 10 mg/kg. There have been postmarketing reports of new onset and worsening heart failure, with and without identifiable precipitating factors. Patients with moderate or severe heart failure taking either REMICADE® or Infliximab (≤ 5 mg/kg) or patients with mild heart failure should be closely monitored and treatment should be discontinued if new or worsening symptoms appear.

HEMATOLOGIC EVENTS

Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported. The causal relationship to REMICADE® and Infliximab therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias or infection. Consider discontinuation of either REMICADE® or Infliximab in patients who develop significant hematologic abnormalities.

HYPERSENSITIVITY

REMICADE® and Infliximab have been associated with hypersensitivity reactions that differ in their time of onset. Anaphylaxis, acute urticaria, dyspnea, and hypotension have occurred in association with infusions of either REMICADE® or Infliximab. Medications for the treatment of hypersensitivity reactions should be available.

CARDIOVASCULAR AND CEREBROVASCULAR REACTIONS DURING AND AFTER INFUSION

Serious cerebrovascular accidents, myocardial ischemia/infarction (some fatal), hypotension, hypertension, and arrhythmias have been reported during and within 24 hours of initiation of either REMICADE® or Infliximab infusions. Cases of transient visual loss have been reported during or within 2 hours of either REMICADE® or Infliximab infusions. Monitor patients during infusion and if a serious reaction occurs, discontinue infusion. Manage reactions according to signs and symptoms.

NEUROLOGIC EVENTS

TNF blockers, including REMICADE® and Infliximab, have been associated with CNS manifestation of systemic vasculitis, seizure, and new onset or exacerbation of CNS demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barré

syndrome. Exercise caution when considering either REMICADE® or Infiximab in patients with these disorders and consider discontinuation if these disorders develop.

CONCURRENT ADMINISTRATION WITH OTHER BIOLOGICS

Concurrent use of either REMICADE® or Infiximab with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as REMICADE® and Infiximab is not recommended because of the possibility of an increased risk of infection. Care should be taken when switching from one biologic to another, since overlapping biological activity may further increase the risk of infection.

AUTOIMMUNITY

Treatment with either REMICADE® or Infiximab may result in the formation of autoantibodies and in the development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

VACCINATIONS AND USE OF LIVE VACCINES/THERAPEUTIC INFECTIOUS AGENTS

Prior to initiating either REMICADE® or Infiximab, update vaccinations in accordance with current vaccination guidelines. Live vaccines or therapeutic infectious agents should not be given with either REMICADE® or Infiximab due to the possibility of clinical infections, including disseminated infections.

At least a 6-month waiting period following birth is recommended before the administration of any live vaccine to infants exposed *in utero* to either REMICADE® or Infiximab.

ADVERSE REACTIONS

In clinical trials, the most common adverse reactions occurring in >10% of REMICADE®- and Infiximab-treated patients included infections (eg, upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

For more information, please see the full [Prescribing Information](#), including Boxed Warning and [Medication Guide](#) for REMICADE® and full [Prescribing Information](#), including Boxed Warning and [Medication Guide](#) for Infiximab. Provide the Medication Guides to your patients and encourage discussion.

References: **1.** American Thoracic Society, Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med.* 2000;161:S221-S247. **2.** See latest Centers for Disease Control guidelines and recommendations for tuberculosis testing in immunocompromised patients.

An Unbranded Treatment Option for an Evolving Market

Janssen's unbranded Infiximab is:



The **same product** as REMICADE®⁴⁻⁶



Produced from the **same** cell line and at the **same** manufacturing sites as REMICADE®⁴



Priced **59% lower** than branded REMICADE®, based on WAC⁴

Unbranded Infiximab provides an additional option that puts patients first by helping keep clinically stable patients on current therapy.

FOR MORE INFORMATION ON Infiximab, CONTACT YOUR JANSSEN REPRESENTATIVE, OR VISIT [Infiximab.com](https://www.infiximab.com)

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References: 1. US Food and Drug Administration. Biosimilar and Interchangeable Biologics: More Treatment Choices. Accessed August 23, 2023. <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices> 2. US Food and Drug Administration. FAQs – Purple Book. Accessed August 23, 2023. <https://purplebooksearch.fda.gov/faqs> 3. Declerck P et al. Biosimilarity versus manufacturing change: two distinct concepts. *Pharm Res*. 2016;33(2):261-268. 4. Data on file. Janssen Biotech, Inc. 5. Infiximab [Prescribing Information]. Horsham, PA; Janssen Biotech, Inc. 6. REMICADE® [Prescribing Information]. Horsham, PA; Janssen Biotech, Inc. 7. Hsia EC, Ruley KM, Rahman MU. Infiximab (Remicade®): from bench to clinical practice. A paradigm shift in rheumatology practice. *APLAR J Dermatol*. 2006;9:107-118.