WELCOME TO AVSOLA®

The treatment just like Remicade® (infliximab)[1,2]

Talk to your doctor if you have any questions about AVSOLA® or your treatment. Nothing in this brochure should be viewed as a substitute for medical advice from a doctor.

This brochure includes information about AVSOLA®, a prescription medicine indicated to treat:[1]

INDICATIONS

AVSOLA® is indicated for:

Moderate to Severe 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

Moderate to Severe 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

Moderate to Severe Ulcerative Colitis (UC): 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 UC who haven't responded well to other therapies

Moderate to Severe 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

Moderate to Severe Rheumatoid Arthritis (RA): Can reduce signs and symptoms, help stop further joint damage, and improve physical function in adult patients with moderately to severely active RA, in combination with methotrexate

Psoriatic Arthritis (PsA): Can reduce signs and symptoms of active arthritis, help stop further joint damage, and improve physical function in adult patients with PsA

Ankylosing Spondylitis (AS): Can reduce signs and symptoms in adult patients with active AS

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

Please see full **Important Safety Information** on page 9 and **full Prescribing Information**.

FDA EXPERTS HAVE AGREED THAT AVSOLA® IS HIGHLY SIMILAR TO REMICADE®

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

AVSOLA® is an infliximab, just like Remicade®[2,3]

FDA APPROVED® as a Remicade® biosimilar

FDA approval means that AVSOLA® is:

- Proven in studies that it is highly similar to Remicade®
- Proven to have similar safety and effectiveness to Remicade®

If Remicade® is helping you, then you may be able to expect similar results with AVSOLA®[4]

SELECTED IMPORTANT SAFETY INFORMATION

AVSOLA® can lower your ability to fight infections. Serious and sometimes fatal events can occur. There have been reports of serious infections, including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that have spread throughout the body or cause infections in certain areas. Lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, and other cancers have been reported in children and adults taking TNF-blockers, including AVSOLA®. Some people with heart failure should not take AVSOLA®. Other serious side effects reported include skin cancer, cervical cancer, hepatitis B, heart problems or stroke within 24 hours of infusion, liver injury, blood problems, nervous system problems, allergic reactions, or lupus-like syndrome.

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AVSOLA® IS PROVEN TO OFFER THE SAME TREATMENT BENEFITS AS REMICADE®

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

AVSOLA® went through many steps to prove it has no clinically meaningful differences from Remicade®[1]

CLINICAL STUDIES PROVED THAT AVSOLA® AND REMICADE® HAVE NO MEANINGFUL DIFFERENCES IN:

1 BIOLOGIC STRUCTURE (both products are infliximab)

2 HOW THEY WORK IN THE BODY

3 TREATMENT RESULTS

SELECTED IMPORTANT SAFETY INFORMATION

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PATIENTS WHO WERE SWITCHED

FROM REMICADE® TO AVSOLA® HAD HIGHLY SIMILAR SIDE EFFECTS & SYMPTOM IMPROVEMENT IN THE APPROVAL STUDY*

*Results were from a study in which 558 patients with moderate-to-severe rheumatoid arthritis were treated with AVSOLA® or Remicade® for 22 weeks, and then half of the patients who began treatment with Remicade® were switched to AVSOLA®.

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

FIND MORE INFORMATION ABOUT BIOSIMILARS HERE

SELECTED IMPORTANT SAFETY INFORMATION *(continued)*

infections in certain areas. Lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, and other cancers have been reported in children and adults taking TNF-blockers, including AVSOLA®. Some people with heart failure should not take AVSOLA®. Other serious side effects reported include skin cancer, cervical cancer, hepatitis B, heart problems or stroke within 24 hours of infusion, liver injury, blood problems, nervous system problems, allergic reactions, or lupus-like syndrome.

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A HIGHLY SIMILAR TREATMENT EXPERIENCE WITH AVSOLA®

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

WHEN SWITCHING TO AVSOLA®:[2,3]

SAME

- **INDICATIONS**
- **STRENGTH**
- **DOSING SCHEDULE**
- **IV ADMINISTRATION**

IV = intravenous.

SELECTED IMPORTANT SAFETY INFORMATION

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AVSOLA® (infliximab-axxq) For Injection 100mg/vial

YOUR AVSOLA® WILL BE ADMINISTERED LIKE YOUR NEXT PLANNED REMICADE® DOSE

SELECTED IMPORTANT SAFETY INFORMATION *(continued)*

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AVSOLA® IS MADE BY AMGEN®, A LEADER IN BIOTECHNOLOGY

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

MORE THAN 40 YEARS
MAKING **BIOLOGIC MEDICINES**

&

MORE THAN 20 YEARS
TREATING PATIENTS WITH **INFLAMMATION DISEASES**

AT AMGEN, WE'RE COMMITTED TO DELIVERING QUALITY PRODUCTS TO EVERY PATIENT, EVERY TIME

Please see the full **Important Safety Information** on page 9 and **full Prescribing Information**.

DEDICATED SUPPORT & RESOURCES FOR AVSOLA® PATIENTS

Amgen provides the same level of patient support for all of its medicines

Your Amgen® SupportPlus Representative is here to help you understand

- **Insurance coverage**
- **Co-pay costs**
- **Deductible costs**

AMGEN® Support+

Call **(866) 264-2778**
Monday to Friday, 9:00 am to 8:00 pm ET

FIND MORE INFORMATION ABOUT AMGEN SUPPORT RESOURCES AT
WWW.AVSOLA.COM/PATIENT/AMGEN-SUPPORT-AND-RESOURCES

Please see the full **Important Safety Information** on page 9 and **full Prescribing Information**.

IMPORTANT SAFETY INFORMATION

Only your doctor can recommend a course of treatment after checking your health condition. AVSOLA® (infliximab-axxq) 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 AVSOLA®.**

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

It is not known if AVSOLA® is safe and effective in children under 6 years of age.

You should discuss any concerns about your health and medical care with your doctor. What should I tell my doctor before I take AVSOLA®?

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 AVSOLA®.
- Lived in a region where certain fungal infections like histoplasmosis, coccidioidomycosis or blastomycosis are common.
- Infections that keep coming back, have 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 AVSOLA®.
- 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 AVSOLA®.
- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using AVSOLA® during your pregnancy. You and your doctor should decide if you should receive AVSOLA® while you are pregnant or breastfeeding. Tell your baby's doctor about your AVSOLA® 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 AVSOLA® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking AVSOLA®.

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

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

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. AVSOLA® 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, 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 during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, 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 most common side effects of infliximab products include respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing and stomach pain.

Please read the full Prescribing Information and Medication Guide for AVSOLA® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

AVSOLA® AND YOU

Continue with a highly similar treatment experience when switching from Remicade®[2-4]

YOUR TREATMENT WITH AVSOLA®

PROVEN TO OFFER THE SAME TREATMENT BENEFITS[1-4]

BACKED BY THE EXPERTS AT AMGEN

DEDICATED SUPPORT RESOURCES

References: 1. US Food and Drug Administration. Guidance for industry: scientific considerations in demonstrating biosimilarity to a reference product. www.fda.gov/downloads/drugs/guidances/ucm291128.pdf. Accessed January 20, 2021. **2.** AVSOLA® (infliximab-axxq) Prescribing Information, Amgen. **3.** Remicade® (infliximab) Prescribing Information, Janssen Biotech. **4.** Genovese MC, Sanchez-Burson J, Oh M, et al. Comparative clinical efficacy and safety of the proposed biosimilar ABP 710 with infliximab reference product in patients with rheumatoid arthritis. *Arthritis Res Ther.* 2020;22:60. doi:10.1186/s13075-020-2142-12

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