TAKE THE NEXT STEP WITH AVSOLA™

Your guide to understanding and starting treatment with AVSOLA™

Patient portrayals

Please see the full Important Safety Information on pages 14-16.
WHAT WILL I FIND IN THIS BROCHURE?

This brochure includes information about AVSOLA™, a prescription medicine indicated to treat:

**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 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 patients with PsA

**Ankylosing Spondylitis (AS):** Can reduce signs and symptoms in 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

This brochure offers resources, instructions, and support as you begin your treatment with AVSOLA™.

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**Select 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. Lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, and other cancers have been reported in children and adults taking TNF-blocker medicines. 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.

Please see the full **Important Safety Information** on pages 14-16.
WHAT IS AVSOLA™?

AVSOLA™ is a medicine your doctor may prescribe to treat chronic inflammation disease. AVSOLA™ is a biosimilar of the biologic medicine Remicade® (infliximab).

A biosimilar is a complex medicine
A biosimilar is a highly similar version of an approved biologic medicine. Biologics and biosimilars are both made from living cells. Biosimilars must provide the same treatment benefit as the original biologic.

Compared with their original biologics, biosimilars:
- Are given the same way
- Provide the same treatment benefit
- Have the same potential side effects

AVSOLA™ was carefully made and rigorously tested
The FDA approved AVSOLA™ as a biosimilar to Remicade® because it:
- Works similarly in the body
- Is similarly effective
- Has similar safety

HOW DOES AVSOLA™ TREAT INFLAMMATION?

How do inflammation diseases affect the body?
When you have an inflammation disease, the body makes too much of a certain protein called tumor necrosis factor-alpha (TNF-α). This can cause your immune system to attack healthy parts of the body, which leads to inflammation and pain.

AVSOLA™ targets and blocks extra TNF-α
Blocking extra TNF-α can help relieve symptoms like inflammation, and prevent further joint damage.

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Please see the full Important Safety Information on pages 14-16.
WHY AVSOLA™?

AVSOLA™ is approved by the FDA as a biosimilar to Remicade®, and to treat the same inflammation diseases. It was tested worldwide in RA patients and was shown to be as safe and effective.\(^{1,8}\)

HOW AVSOLA™ CAN HELP IN INFLAMMATORY ARTHRITIS DISEASES\(^{1,1}\)

**Moderately to Severely Active Rheumatoid Arthritis (RA)\(^*\)**

*In combination with methotrexate.

Improvements in:
- Pain and stiffness
- Physical function

Helps stop further joint damage

**Active Psoriatic Arthritis (PsA)**

Improvements in:
- Pain and stiffness
- Skin symptoms

Helps stop further joint damage

**Active Ankylosing Spondylitis (AS)**

Improvements in:
- Pain and inflammation

**How AVSOLA™ Can Help in Inflammatory Bowel Diseases\(^1,1\)**

**Moderately to Severely Active Crohn’s Disease (CD)**

Improvements in:
- Signs and symptoms

**Moderately to Severely Active Ulcerative Colitis (UC)**

Improvements in:
- Signs and symptoms
- Digestive tract healing

AVSOLA™ HAS SIMILAR SAFETY COMPARED TO REMICADE®\(^8\)

Can I take AVSOLA™ if I’ve already started Remicade®?\(^8\)

In a comparative study, patients who switched from Remicade® to AVSOLA™ experienced similar safety and effectiveness.\(^8\)

You and your doctor may consider treatment with AVSOLA™ if you are new to infliximab therapy, or if you are currently stable on Remicade®.

*Individual results may vary.

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Select Important Safety Information (continued)

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.

*Individual results may vary.

Please see the full Important Safety Information on pages 14-16.
**HOW DO I TAKE AVSOLATM?**

**Your dose of AVSOLATM will be based on your weight**

After you are prescribed AVSOLATM, your healthcare team will weigh you and check your vitals. Then, AVSOLATM is given to you by a doctor or nurse as an intravenous (IV) infusion. You may receive medicine before your infusion to prevent or reduce side effects.1

**Preparing for your infusion**

- **Wear comfortable, loose-fitting clothing**
- **Ask your doctor if you should eat, drink, or take any medications before arriving**
- **Bring some things to help pass the time** (Like books, a tablet, or music)

**During your infusion**

- **Your hand or arm will be sterilized, and the IV will be inserted and secured with tape**
- **The infusion will take around 2 hours.1** Your doctor or nurse will be there to make sure everything goes smoothly

**Your infusion schedule1**

- **Over the first 6 weeks,** you will receive 3 starter doses (At weeks 0, 2, and 6)
- **After the starter doses, you will receive additional treatment once every 4,6, or 8 weeks**

**AFTER YOUR STARTER DOSES, AS FEW AS 7 TREATMENTS A YEAR†**

**Select Important Safety Information**

AVSOLATM 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. Lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, and other cancers have been reported in children and adults taking TNF-blocker medicines. Some people with heart failure should not take AVSOLATM. Other serious side effects reported include skin cancer, cervical cancer, hepatitis B, heart problems or stroke within 24 hours of infusion, liver injury,

**What if my doctor switches me from Remicade® to AVSOLATM?**

*Because AVSOLATM is a biosimilar to Remicade®, your infusion schedule may not change. Your doctor will determine the right dose and schedule of AVSOLATM for you.1,8*

**Select Important Safety Information (continued)**

blood problems, nervous system problems, allergic reactions, or lupus-like syndrome.

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*Some moderate to severe rheumatoid arthritis patients may receive treatment every 4 weeks.
†Treatment schedule may vary by condition.

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Please see the full Important Safety Information on pages 14-16.
WHAT IF I NEED ADDITIONAL SUPPORT?

Amgen is deeply committed to supporting patients like you through your treatment with AVSOLA™

Amgen brings treatment options to millions of people with inflammation diseases.

OVER 40 YEARS of biologic experience

Manufacturer of 18 INNOVATOR BIOLOGICS

AMGEN IS COMMITTED TO DELIVERING QUALITY PRODUCTS TO EVERY PATIENT, EVERY TIME

To learn more, visit www.AVSOLA.com/patients

AMGEN ASSIST*

If you’ve been prescribed AVSOLA™, you may have questions about your co-pay, insurance, or your options if you do not have insurance. Your Patient Access Specialist is here to help.

Patient Access Specialists can help you understand:

INSURANCE COVERAGE  CO-PAY COSTS  DEDUCTIBLE COSTS

Referrals for day-to-day living*

We can help refer you to independent nonprofit organizations that may provide you with community resources, one-on-one counseling services, and local support groups.

Call 1-866-AMG-ASST (1-866-264-2778) Monday to Friday, 9:00 am to 8:00 pm ET

The AVSOLA™ Co-pay Program can help eligible commercially insured patients lower their out-of-pocket medication costs for AVSOLA™, including deductible, co-insurance, and co-payment.†

• Pay as little as $5 out-of-pocket for each treatment, up to the program maximum. See summary of Terms and Conditions on the following page or full Terms and Conditions at AVSOLASupport.com

• No income eligibility requirement

†Program covers out-of-pocket medication costs for AVSOLA™ only up to program maximums. Program does not cover any other costs related to office visits or administration of AVSOLA™. Other restrictions may apply. See enclosed for details. Not valid where prohibited by law.

The AVSOLA™ Co-Pay Program Prepaid MasterCard® is issued by Comerica Bank pursuant to license by MasterCard® International incorporated. No cash or ATM access. MasterCard® is a registered trademark of MasterCard® International Incorporated. This card can be used only to cover co-payment for eligible prescriptions covered under the program at participating merchant locations where Debit MasterCard® is accepted.

Call 1-866-AMG-ASST (1-866-264-2778)
Monday to Friday, 9:00 am to 8:00 pm ET, or visit AVSOLASupport.com

*Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits’ criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

Please see the full Important Safety Information on pages 14-16.
WHAT IF I NEED ADDITIONAL SUPPORT?

SUMMARY OF TERMS AND CONDITIONS

It is important that every patient read and understand the full AVSOLA™ Co-Pay Card Terms and Conditions. The following summary is not a substitute for reviewing the Terms and Conditions in their entirety.

As further described below, in general:

• The AVSOLA™ Co-Pay Card is open to patients with commercial insurance, regardless of financial need. The program is not valid for patients whose AVSOLA™ prescription is paid for in whole or in part by Medicare, Medicaid, or any other federal or state healthcare program. It is not valid for cash paying patients or where prohibited by law.

• The AVSOLA™ Co-pay Card may help lower your AVSOLA™ out-of-pocket medication costs. Out-of-pocket costs include co-payment, co-insurance, and deductible out-of-pocket costs. The AVSOLA™ Co-Pay Card does not cover any other costs related to office visits or administration of AVSOLA™. The AVSOLA™ Co-Pay Card provides support up to the Maximum Program Benefit or Patient Total Program Benefit. If a patient’s commercial insurance plan imposes different or additional requirements on patients who receive AVSOLA™ Co-Pay Card benefits, Amgen has the right to reduce or eliminate those benefits. Whether you are eligible to receive the Maximum Program Benefit or Patient Total Program Benefit is determined by the type of plan coverage you have. Please ask your AVSOLA™ Support Representative to help you understand eligibility for the AVSOLA™ Co-Pay Card, whether your particular insurance coverage is likely to result in your reaching the Maximum Program Benefit or your Patient Total Program Benefit amount by calling 1-866-264-2778.

• AVSOLA™ patients pay $5 out-of-pocket for each treatment, and Amgen will pay the remaining eligible out-of-pocket costs on behalf of the patient until the Amgen payments have reached either the Maximum Program Benefit or the Patient Total Program Benefit. Patients are responsible for all amounts that exceed this limit.

• Ongoing activation of the AVSOLA™ Co-Pay Card is contingent on the submission of the required Explanation of Benefits (EOB) form by the healthcare provider’s office within 180 days of the use of the AVSOLA™ Co-Pay Card. Patients will be responsible for reimbursing the program for all amounts paid out if the EOB for the date of service is not received within 180 days.

See full Terms and Conditions at AVSOLASupport.com.
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.

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. 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.

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.

References:
1. AVSOLA™ (infliximab-axxq) Prescribing Information, Amgen.  
8. Data on file, Amgen; [CSR 20140111, 2019].

Please see the full Important Safety Information on pages 14-16, and Prescribing Information, including Boxed WARNINGS.

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

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