TAKE THE NEXT STEP WITH AVSOLA®

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

Your guide to understanding and starting treatment with AVSOLA®



Patient portrayals

AMGEN®

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:[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

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

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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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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).[1]

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.[2]

Compared with their original biologics, biosimilars:[3]

- ✓ 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:[1]

- ✓ Works similarly in the body
- ✓ Is similarly effective
- ✓ Has similar safety



The FDA sets rigorous standards *for making and approving biosimilars so patients and healthcare professionals can* ***rely on the safety and effectiveness of the biosimilar****, just as they would with the original biologic*[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

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.[5,6]

AVSOLA® targets and blocks extra TNF-α

Blocking extra TNF-α can help relieve symptoms like inflammation, and prevent further joint damage.[1,7]



*AVSOLA® targets **specific parts of the immune system** that cause inflammation*[1]

FDA = Food and Drug Administration.

SELECTED IMPORTANT SAFETY INFORMATION *(continued)*

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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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,*]

Moderately to Severely Active Rheumatoid Arthritis (RA)*



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

*In combination with methotrexate.

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

HOW AVSOLA® CAN HELP IN INFLAMMATORY BOWEL DISEASES[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®?

*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.

SELECTED IMPORTANT SAFETY INFORMATION *(continued)*

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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HOW DO I TAKE AVSOLA®?

Your dose of AVSOLA® will be based on your weight

After you are prescribed AVSOLA®, your healthcare team will weigh you and check your vitals. Then, AVSOLA® 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

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.

Your infusion schedule[1]

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†



What if my doctor switches me from Remicade® to AVSOLA®?

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



SAME WEIGHT-BASED DOSING



SAME AMOUNT OF INFUSION TIME



TYPICALLY AVAILABLE AT THE SAME INFUSION CENTER

*Some moderate to severe rheumatoid arthritis patients may receive treatment every 4 weeks.

†Treatment schedule may vary by condition.

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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® Support+

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 Amgen® SupportPlus Representative is here to help.

Amgen® SupportPlus Representatives can help you understand:

INSURANCE COVERAGE	**CO-PAY COSTS**	**DEDUCTIBLE COSTS**

Patient Assistance Programs*

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

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

*Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

The Amgen® SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.*

- **Pay as little as $0* out-of-pocket for each dose**
- **Can be applied to deductible, co-insurance, and co-payment***
- **No income eligibility requirement**



Call **(866) 264-2778** Monday to Friday, 9:00 am to 8:00 pm ET, or visit **AmgenSupportPlus.com/copay**

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

Please see the full **Important Safety Information** on pages 14-16.

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WHAT IF I NEED ADDITIONAL SUPPORT?

AMGEN® SUPPORTPLUS CO-PAY CARD TERMS AND CONDITIONS

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

These terms and conditions apply to the following products:
BLINCYTO® (blinatumomab), IMLYGIC® (talimogene laherparepvec), KANJINTI® (trastuzumab-anns), KYPROLIS® (carfilzomib), LUMAKRAS® (sotorasib), MVASI® (bevacizumab-awwb), NEULASTA® (pegfilgrastim), NEUPOGEN® (filgrastim), NPLATE® (romiplostim), PROLIA® (denosumab), RIABNI™ (rituximab-arrx), VECTIBIX® (panitumumab), XGEVA® (denosumab), EVENITY® (romosozumab-aqqg), and AVSOLA® (infliximab-axxq)

As further described below, in general:

- The Amgen SupportPlus Co-Pay Card is open to patients with commercial insurance that covers an Amgen SupportPlus product listed above, regardless of financial need. The program is not valid for patients whose prescription for an Amgen SupportPlus product 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. (See ELIGIBILITY section in the full Terms & Conditions.)
- The Amgen SupportPlus Co-Pay Card may help lower your Amgen SupportPlus product out-of-pocket medication costs. Out-of-pocket costs may include co-payment, co-insurance, and deductible out-of-pocket costs. The Amgen SupportPlus Co-Pay Card does not cover any other costs related to office visits or administration of the product. The Amgen SupportPlus 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 Amgen SupportPlus Co-Pay Card benefits, Amgen has the right to modify or eliminate those benefits. Whether you are eligible to receive the Maximum Program Benefit or Patient Total

AMGEN® SUPPORTPLUS CO-PAY CARD TERMS AND CONDITIONS *(CONTINUED)*

Program Benefit is determined by the type of plan coverage you have. Please ask your Amgen SupportPlus Support Representative to help you understand eligibility for the Amgen SupportPlus 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 (866) 264-2778. (See PROGRAM BENEFITS section in the full Terms & Conditions.)

- Amgen SupportPlus patients may pay as little as:
  - $0 out-of-pocket for each dose or cycle of the Amgen SupportPlus product (excluding Prolia® and EVENITY®)
  - $25 out-of-pocket for each dose of Prolia® or EVENITY®

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 and/or the Patient Total Program Benefit. Patients are responsible for all amounts that exceed this limit. Please ask your Amgen SupportPlus Support Representative to help you understand eligibility for the Amgen SupportPlus Co-Pay Card by calling (866) 264-2778. (See PROGRAM DETAILS section in the full Terms & Conditions.)

Program coverage through the Amgen SupportPlus Co-Pay Card is contingent on (1) the submission of the required Explanation of Benefits (EOB) form within 180 days of the date of approval documented on the EOB for medical benefit claims or (2) the submission of the claim within 180 days of the date of service for pharmacy benefit claims. (See PROGRAM DETAILS section in the full Terms & Conditions.)

See Amgensupportplus.com/copay for full Terms and Conditions.

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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

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Also tell your doctor if you: *(continued)*

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.

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IMPORTANT SAFETY INFORMATION *(CONTINUED)*

- 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.

References: 1. AVSOLA® (infliximab-axxq) Prescribing Information, Amgen. **2.** 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 October 16, 2019. **3.** US Food and Drug Administration. Patient materials. www.fda.gov/drugs/biosimilars/patient-materials. Accessed October 16, 2019. **4.** US Food and Drug Administration. What is a biosimilar? www.fda.gov/media/108905/download. Accessed October 21, 2019. **5.** Crohn's and Colitis Foundation. Fact sheet - biologics. www.crohnscolitisfoundation.org/sites/default/files/2019-06/medications-biologic-therapy.pdf. Accessed October 16, 2019. **6.** Centers for Disease Control and Prevention. Rheumatoid arthritis. www.cdc.gov/arthritis/basics/rheumatoid-arthritis.html. Accessed October 16, 2019. **7.** Schett G, Coates LC, Ash ZR, Finzel S, Conaghan PG. Structural damage in rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis: traditional views, novel insights gained from TNF blockade, and concepts for the future. *Arthritis Res Ther.* 2011;13:1-9. **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**.

AVSOLA® IS HERE FOR YOU



AVSOLA® is FDA approved as a biosimilar to Remicade® because it:[1]

- **WORKS SIMILARLY IN THE BODY**
- **IS SIMILARLY EFFECTIVE**
- **HAS SIMILAR SAFETY**

Amgen® SupportPlus can help you understand:

- Insurance coverage
- Deductible costs
- Co-pay costs

FOR SUPPORT, CALL
(866) 264-2778

To learn more, visit **WWW.AVSOLA.COM/PATIENTS**

SELECTED IMPORTANT SAFETY INFORMATION

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