MEDICATION GUIDE
AVSOLA® (av-SOH-luh)
(infliximab-axxq)

for injection, for intravenous use

Read the Medication Guide that comes with AVSOLA before you receive the first treatment, and before each time you get a treatment of AVSOLA. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about AVSOLA?
AVSOLA may cause serious side effects, including:

1. Risk of infection
AVSOLA is a medicine that affects your immune system. AVSOLA can lower the ability of your immune system to fight infections. Serious infections have happened in patients receiving AVSOLA. These infections include tuberculosis (TB) and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some patients have died from these infections.

- Your doctor should test you for TB before starting AVSOLA.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with AVSOLA.

Before starting AVSOLA, tell your doctor if you:
- think you have an infection. You should not start receiving AVSOLA if you have any kind of infection.
- are being treated for an infection.
- have signs of an infection, such as a fever, cough, flu-like symptoms.
- have any open cuts or sores on your body.
- get a lot of infections or have infections that keep coming back.
- have diabetes or an immune system problem. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may develop or become more severe if you receive AVSOLA. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your doctor.
- have or have had hepatitis B.
- use the medicines KINERET (anakinra), ORENCIA (abatacept), ACTEMRA (tocilizumab), or other medicines called biologics used to treat the same conditions as AVSOLA.

After starting AVSOLA, if you have an infection, any sign of an infection including a fever, cough, flu-like symptoms, or have open cuts or sores on your body, call your doctor right away. AVSOLA can make you more likely to get infections or make any infection that you have worse.

2. Risk of Cancer
- There have been cases of unusual cancers in children and teenage patients using tumor necrosis factor (TNF) blocker medicines, such as AVSOLA.
- For children and adults receiving TNF blocker medicines, including AVSOLA, the chances of getting lymphoma or other cancers may increase.
- Some people receiving TNF blockers, including AVSOLA, developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men. Also, most people were being treated for Crohn's disease or ulcerative colitis with a TNF blocker and another medicine called azathioprine or 6-mercaptopurine.
- People who have been treated for rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis for a long time may be more likely to develop lymphoma. This is especially true for people with very active disease.
- Some people treated with infliximab products, such as AVSOLA, have developed certain kinds of skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with AVSOLA, tell your doctor.
- Patients with Chronic Obstructive Pulmonary Disease (COPD), a specific type of lung disease, may have an increased risk for getting cancer while being treated with AVSOLA.
- Some women being treated for rheumatoid arthritis with infliximab products have developed cervical cancer. For

women receiving AVSOLA, including those over 60 years of age, your doctor may recommend that you continue to be regularly screened for cervical cancer.
- Tell your doctor if you have ever had any type of cancer. Discuss with your doctor any need to adjust medicines you may be taking.

See the section "**What are the possible side effects of AVSOLA?**" below for more information.

What is AVSOLA?

AVSOLA is a prescription medicine that is approved for patients with:
- 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 in adults.
- Psoriatic Arthritis in adults.
- Plaque Psoriasis - adult patients with plaque psoriasis that is chronic (does not go away), severe, extensive, and/or disabling.
- Ulcerative Colitis - children 6 years and older and adults with moderately to severely active ulcerative colitis who have not responded well to other medicines.

AVSOLA blocks the action of a protein in your body called tumor necrosis factor-alpha (TNF-alpha). TNF-alpha is made by your body's immune system. People with certain diseases have too much TNF-alpha that can cause the immune system to attack normal healthy parts of the body. AVSOLA can block the damage caused by too much TNF-alpha.

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

Who should not receive AVSOLA?

You should not receive AVSOLA if you have:
- heart failure, unless your doctor has examined you and decided that you are able to receive AVSOLA. Talk to your doctor about your heart failure.
- had an allergic reaction to infliximab products, or any of the ingredients in AVSOLA. See the end of this Medication Guide for a complete list of ingredients in AVSOLA.

What should I tell my doctor before starting treatment with AVSOLA?

Your doctor will assess your health before each treatment.

Tell your doctor about all of your medical conditions, including if you:
- have an infection (see "**What is the most important information I should know about AVSOLA?**").
- have other liver problems including liver failure.
- have heart failure or other heart conditions. If you have heart failure, it may get worse while you receive AVSOLA.
- have or have had any type of cancer.
- have had phototherapy (treatment with ultraviolet light or sunlight along with a medicine to make your skin sensitive to light) for psoriasis. You may have a higher chance of getting skin cancer while receiving AVSOLA.
- have COPD, a specific type of lung disease. Patients with COPD may have an increased risk of getting cancer while receiving AVSOLA.
- have or have had a condition that affects your nervous system such as:
    - multiple sclerosis, or Guillain-Barré syndrome, or
    - if you experience any numbness or tingling, or
    - if you have had a seizure.
- have recently received or are scheduled to receive a vaccine. **Adults and children receiving AVSOLA should not receive live vaccines (for example, the Bacille Calmette-Guérin [BCG] vaccine) or treatment with a weakened bacteria** (such as BCG for bladder cancer). Adults and children should have all of their vaccines brought up to date before starting treatment with AVSOLA.
- are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed. You and your doctor should decide if you should receive AVSOLA while you are pregnant or breastfeeding.

If you have a baby and you were receiving AVSOLA during your pregnancy, it is important to tell your baby's doctor and other health care professionals about your AVSOLA use so they can decide when your baby should receive any vaccine. Certain vaccinations can cause infections.

If you received AVSOLA while you were pregnant, your baby may be at higher risk for getting an infection. 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. This includes live vaccines such as the BCG, rotavirus, or any other live vaccines. For other types of vaccines, talk with your doctor.

How should I receive AVSOLA?

- You will be given AVSOLA through a needle placed in a vein (IV or intravenous infusion) in your arm.
- Your doctor may decide to give you medicine before starting the AVSOLA infusion to prevent or lessen side effects.
- Only a healthcare professional should prepare the medicine and administer it to you.
- AVSOLA will be given to you over a period of about 2 hours.
- If you have side effects from AVSOLA, the infusion may need to be adjusted or stopped. In addition, your healthcare professional may decide to treat your symptoms.
- A healthcare professional will monitor you during the AVSOLA infusion and for a period of time afterward for side effects. Your doctor may do certain tests while you are receiving AVSOLA to monitor you for side effects and to see how well you respond to the treatment.
- Your doctor will determine the right dose of AVSOLA for you and how often you should receive it. Make sure to discuss with your doctor when you will receive infusions and to come in for all your infusions and follow-up appointments.

What should I avoid while receiving AVSOLA?

Do not take AVSOLA together with medicines such as KINERET (anakinra), ORENCIA (abatacept), ACTEMRA (tocilizumab), or other medicines called biologics that are used to treat the same conditions as AVSOLA.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. These include any other medicines to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis or psoriasis.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

What are the possible side effects of AVSOLA?

AVSOLA can cause serious side effects, including:

See "**What is the most important information I should know about AVSOLA?**"

Serious Infections

- Some patients, especially those 65 years and older have had serious infections while receiving infliximab products, such as AVSOLA. These serious infections include TB and infections caused by viruses, fungi, or bacteria that have spread throughout the body or cause infections in certain areas (such as skin). Some patients die from these infections. If you get an infection while receiving treatment with AVSOLA your doctor will treat your infection and may need to stop your AVSOLA treatment.
- Tell your doctor right away if you have any of the following signs of an infection while receiving or after receiving AVSOLA:
  - a fever
  - feel very tired
  - have a cough
  - have flu-like symptoms
  - warm, red, or painful skin
- Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with AVSOLA and during treatment with AVSOLA.
- Even if your TB test is negative, your doctor should carefully monitor you for TB infections while you are receiving AVSOLA. Patients who had a **negative** TB skin test before receiving infliximab products have developed active TB.
- If you are a chronic carrier of the hepatitis B virus, the virus can become active while you are being treated with AVSOLA. In some cases, patients have died as a result of hepatitis B virus being reactivated. Your doctor should do a blood test for hepatitis B virus before you start treatment with AVSOLA and occasionally while you are being treated. Tell your doctor if you have any of the following symptoms:
  - feel unwell
  - poor appetite
  - tiredness (fatigue)
  - fever, skin rash, or joint pain

Heart Failure
If you have a heart problem called congestive heart failure, your doctor should check you closely while you are receiving AVSOLA. Your congestive heart failure may get worse while you are receiving AVSOLA. Be sure to tell your doctor of any new or worse symptoms including:

- shortness of breath
- sudden weight gain
- swelling of ankles or feet

Treatment with AVSOLA may need to be stopped if you get new or worse congestive heart failure.

Other Heart Problems
Some patients have experienced a heart attack (some of which led to death), low blood flow to the heart, or abnormal heart rhythm within 24 hours of beginning their infusion of infliximab products. Symptoms may include 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. Tell your doctor right away if you have any of these symptoms.

Liver Injury
Some patients receiving infliximab products have developed serious liver problems. Tell your doctor if you have:

- jaundice (skin and eyes turning yellow)
- fever
- dark brown-colored urine
- extreme tiredness (severe fatigue)
- pain on the right side of your stomach area (right-sided abdominal pain)

Blood Problems
In some patients receiving infliximab products, the body may not make enough of the blood cells that help fight infections or help stop bleeding. Tell your doctor if you:

- have a fever that does not go away
- look very pale
- bruise or bleed very easily

Nervous System Disorders
Some patients receiving infliximab products have developed problems with their nervous system. Tell your doctor if you have:

- changes in your vision
- seizures
- numbness or tingling in any part of your body
- weakness in your arms or legs

Some patients have experienced a stroke within approximately 24 hours of their infusion with infliximab products. Tell your doctor right away if you have symptoms of a stroke which may include: 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
Some patients have had allergic reactions to infliximab products. Some of these reactions were severe. These reactions can happen while you are getting your AVSOLA treatment or shortly afterward. Your doctor may need to stop or pause your treatment with AVSOLA and may give you medicines to treat the allergic reaction. Signs of an allergic reaction can include:

- hives (red, raised, itchy patches of skin)
- high or low blood pressure
- difficulty breathing
- fever
- chest pain
- chills

Some patients treated with infliximab products have had delayed allergic reactions. The delayed reactions occurred 3 to 12 days after receiving treatment with infliximab products. Tell your doctor right away if you have any of these signs of delayed allergic reaction to AVSOLA:

- fever
- muscle or joint pain
- rash
- swelling of the face and hands
- headache
- difficulty swallowing
- sore throat

Lupus-like Syndrome
Some patients have developed symptoms that are like the symptoms of Lupus. If you develop any of the following symptoms, your doctor may decide to stop your treatment with AVSOLA.

- 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
Some people receiving infliximab products had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps on the skin that are filled with pus. Your doctor may decide to stop your treatment with AVSOLA.

The most common side effects of infliximab products include:

- respiratory infections, such as sinus infections and sore throat
- headache
- coughing
- stomach pain

Infusion reactions can happen up to 2 hours after your infusion of AVSOLA.
Symptoms of infusion reactions may include:

- fever
- chills
- chest pain
- low blood pressure or high blood pressure
- shortness of breath
- rash
- itching

Children with Crohn's disease who received infliximab showed some differences in side effects of treatment compared with adults with Crohn's disease. The side effects that happened more in children were: anemia (low red blood cells), leukopenia (low white blood cells), flushing (redness or blushing), viral infections, neutropenia (low neutrophils, the white blood cells that fight infection), bone fracture, bacterial infection and allergic reactions of the breathing tract. Among patients who received infliximab for ulcerative colitis in clinical studies, more children had infections as compared with adults.
Tell your doctor about any side effect that bothers you or does not go away.
These are not all of the side effects with AVSOLA. Ask your doctor or pharmacist for more information.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about AVSOLA
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

You can ask your doctor or pharmacist for information about AVSOLA that is written for health professionals.

For more information go to www.AVSOLA.com, or call 1- 800-77-AMGEN (1-800-772-6436).

What are the ingredients in AVSOLA?
The active ingredient is infliximab-axxq.

The inactive ingredients in AVSOLA include: dibasic sodium phosphate anhydrous, monobasic sodium phosphate monohydrate, polysorbate 80, and sucrose. No preservatives are present.

AVSOLA® (infliximab-axxq)
Manufactured by: Amgen, Inc. One Amgen Center Drive, Thousand Oaks, CA 91320-1799
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