HUMIRA® (HU-MARE-AH)

(adalimumab)

Patient Information

Read the Patient Information that comes with HUMIRA before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment with HUMIRA.

What is the most important information I should know about HUMIRA?

HUMIRA is a medicine that affects your immune system. HUMIRA can lower the ability of your immune system to fight infections. Serious infections, including tuberculosis (TB) have happened in patients receiving HUMIRA. Some patients have died from these infections.

Before starting HUMIRA, tell your doctor if you:

- think you have an infection
- are being treated for an infection
- have signs of an infection, such as a fever, cough, or 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 or had hepatitis B infection
- have TB, or have been in close contact with someone who has TB. Your doctor should test you for TB before starting HUMIRA. If your doctor prescribes any medicine for the treatment of TB, you should start taking it before starting HUMIRA and take the full course of TB medicine prescribed.
- take the medicine Kineret (anakinra)

After starting HUMIRA, if you get an infection, any sign of an infection including a fever, cough, flu-like symptoms, or have any open cuts or sores on your body, call your doctor right away.

HUMIRA can make you more likely to get infections or make any infection that you may have worse.

What is HUMIRA?

HUMIRA is a medicine called a Tumor Necrosis Factor (TNF) blocker. HUMIRA is used in adults to reduce the signs and symptoms of:

- moderate to severe rheumatoid arthritis (RA) in adults. HUMIRA can be used alone or with methotrexate or with certain other medicines. HUMIRA may prevent further damage to your bones and joints and may help your ability to perform daily activities.
- psoriatic arthritis (PsA). HUMIRA can be used alone or with certain other medicines. HUMIRA may prevent further damage to your bones and joints and may help your ability to perform daily activities.
- ankylosing spondylitis (AS)

• moderate to severe Crohn's disease (CD) in adults who have not responded well to other treatments.

People with these diseases have too much protein called tumor necrosis factor (TNF), which is made by the body's immune system. HUMIRA can reduce the amount of TNF in the body and block the damage that too much TNF can cause, but it can also lower the ability of the immune system to fight infections. See "What is the most important information I should know about HUMIRA?" and "What are the possible side effects of HUMIRA?"

HUMIRA has not been studied in children.

Who should not take HUMIRA?

Do not take HUMIRA if you have an allergy to HUMIRA or to any of its ingredients (including sodium phosphate, sodium citrate, citric acid, mannitol, and polysorbate 80). The needle cover on the prefilled syringe contains dry natural rubber. Tell your doctor if you have any allergies to rubber or latex.

What should I tell my doctor before starting HUMIRA?

To help your doctor decide if HUMIRA is right for you, before starting HUMIRA tell your doctor about all of your health conditions, including if you:

- have an infection. (See "What is the most important information I should know about HUMIRA?")
- have any numbness or tingling or have a disease that affects your nervous system such as multiple sclerosis
- have heart failure
- are scheduled to have major surgery
- are scheduled for any vaccines. Patients receiving HUMIRA should not receive live vaccines.

Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. HUMIRA should only be used during a pregnancy if needed. Women who are breastfeeding should talk to their doctor about whether or not to use HUMIRA.

Pregnancy Registry: Abbott Laboratories has a registry for pregnant women exposed to HUMIRA. The purpose of this registry is to check the health of the pregnant mother and her child. Talk to your doctor to contact the registry for you at 1-877-311-8972.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Your doctor will tell you if it is okay to take your other medicines while taking HUMIRA. Especially, tell your doctor if you take:

• **Kineret (anakinra).** You may have a higher chance for serious infections and a low white blood cell count when taking HUMIRA with Kineret.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.