

## Adalimumab (Humira)

### WHAT IS IT?

Adalimumab (also known by its brand name Humira) is a biologic medication that was first approved for rheumatoid arthritis in 2002 by the U.S. Food and Drug Administration (FDA). It was approved for psoriatic arthritis in 2005 and for psoriasis in 2008. It is also approved for treating juvenile idiopathic arthritis, ankylosing spondylitis and Crohn's disease. Adalimumab is available by prescription.

### HOW DOES IT WORK?

Adalimumab blocks tumor necrosis factor-alpha (TNF-alpha), a chemical "messenger" in the immune system that signals other cells to cause inflammation. There is too much TNF-alpha in the skin and joints of people with psoriasis and psoriatic arthritis. Adalimumab helps lower the amount of TNF-alpha, which interrupts the inflammatory cycle of psoriasis and psoriatic arthritis. This leads to improvement for many people who take it.

### WHO CAN TAKE IT?

Adalimumab is prescribed for adults with moderate to severe psoriasis; it can help reduce the appearance of lesions on the skin. It is also prescribed for people with active psoriatic arthritis; it may prevent further joint damage.

### WHO SHOULD NOT TAKE IT?

- People with active serious infections or a history of recurrent infections
- People with a history of heart failure
- People with multiple sclerosis or other similar types of demyelinating neurologic diseases

Caution is advised for people who experience any numbness or tingling; have ever had a disease that affects the nervous system; and the elderly. The impact of adalimumab on pregnant women or developing fetuses is not known, nor is it known if the medication passes into breast milk in nursing women. If you are pregnant or planning to become pregnant, talk to your doctor.

### HOW IS IT USED?

Adalimumab is given at home by an injection under the skin. The recommended dose for psoriasis is 80 milligrams (mg) on Day 1, and then 40 mg every other week beginning on Day 8. The recommended dose for patients with psoriatic arthritis is 40 mg every other week. Adalimumab is designed to be taken continuously to maintain improvement.

### CAN IT BE USED WITH OTHER TREATMENTS?

Adalimumab is prescribed by itself or in combination with methotrexate, a systemic medication prescribed for psoriasis and psoriatic arthritis. It is also safe to use with phototherapy, topical treatments or pain relievers, such as nonsteroidal anti-inflammatory drugs (NSAIDs). Talk to your doctor about any other medications, vitamins or supplements you may be taking.

### SIDE EFFECTS

The most common side effects are:

- upper respiratory infections
- abdominal pain
- headache
- rash
- injection site reactions
- urinary tract infection

These side effects were generally mild and did not cause most patients to stop taking adalimumab. These happened most often after the first dose and may decrease after additional doses.

## EFFECTIVENESS:

### Psoriasis severity score

- Usually determined by examining the degree of redness, shedding, plaque thickness and affected body surface area. Some scores take into consideration itching and the disease's effect on quality of life.
- In clinical trials, 70 percent of patients taking the recommended dose saw 75 percent improvement in psoriasis severity scores after 3 months.

### Arthritis severity score

- Usually determined by examining swelling in and around the joints and taking into consideration joint tenderness, pain, physical function and morning stiffness.
- In clinical trials, nearly two out of five patients achieved 50 percent improvement in arthritis severity scores.

## RISKS

Adalimumab is not recommended for someone with an active infection or a history of recurring infections. Tell your doctor if you have a fever, cough, flu-like symptoms, feel very tired, or have warm, red, or painful skin.

People should be evaluated for latent TB infections by getting a TB skin test prior to treatment with adalimumab. Doctors may also order a chest X-ray before starting treatment. Hidden TB must be treated before people can begin taking adalimumab.

There have been cases of certain skin cancers in people taking adalimumab. These are generally not life threatening if treated. Tell your doctor if you have a bump or an open sore that doesn't heal.

There is the risk of an allergic reaction to this drug. Signs of a serious allergic reaction include a skin rash, a swollen face, or trouble breathing.

Some people taking a TNF-alpha blocker such as adalimumab have reported reactivation of hepatitis B virus. Some of these cases have been fatal. Tell your doctor if you know or think you may be a carrier of hepatitis B. Tell your doctor if you experience signs of hepatitis B infection, such as feeling unwell, poor appetite and tiredness.

In some people taking adalimumab, the body may not make enough of the blood cells that help stop bleeding. Tell your doctor if you have a persistent fever, look very pale or bruise or bleed very easily.

There have been reports of new or worsening heart failure in people taking adalimumab. Tell your doctor if you have shortness of breath, sudden weight gain or swelling of your ankles or feet.

Some individuals developed lupus-like symptoms that decreased after stopping treatment. Tell your doctor if you develop chest pains that do not go away, shortness of breath, joint pain, or a rash on your cheeks or arms that is sensitive to the sun.

**For detailed information on side effects and safety, talk to your doctor.**

## PATIENT ASSISTANCE INFORMATION

Abbott has a special program where patients can get help with insurance issues or find financial assistance if they cannot afford adalimumab. Call 1.800.4HUMIRA (1.800.448.6472) or visit [www.myhumira.com](http://www.myhumira.com) for more information.

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