

Announcing

HUMIRA[®] (adalimumab) Psoriasis Starter Package

HUMIRA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

► Recommended Dosing for Moderate to Severe Chronic Plaque Psoriasis

The recommended dosing of HUMIRA for adult patients with moderate to severe chronic plaque psoriasis is:

- **Prescription 1**
(Starting dose) **Disp: 1 HUMIRA Psoriasis Starter Package (4 x 40-mg Pens).**
Sig: Inject two 40-mg Pens SC for first dose (Day 1).
Inject one 40-mg Pen SC one week after first dose (Day 8).
Inject one 40-mg Pen SC three weeks after first dose (Day 22).
- **Prescription 2**
(Maintenance dose) **Disp: 1 HUMIRA Pen (2 x 40-mg Pens) Box.**
Sig: Inject one 40-mg Pen SC every other week starting two weeks after last dose.

► How Supplied

HUMIRA Psoriasis Starter Package (NDC # 0074-4339-07) = HUMIRA is dispensed in a carton containing four alcohol preps and four dose trays. Each dose tray consists of a single-use pen, containing a 1-mL prefilled glass syringe with a fixed 27 gauge ½ inch needle, providing 40 mg (0.8 mL) of HUMIRA.

HUMIRA Pen Carton (NDC # 0074-4339-02) = HUMIRA is dispensed in a carton containing two alcohol preps and two dose trays. Each dose tray consists of a single-use pen, containing a 1-mL prefilled glass syringe with a fixed 27 gauge ½ inch needle, providing 40 mg (0.8 mL) of HUMIRA.

Prefilled Syringe Carton—40 mg (NDC # 0074-3799-02) = HUMIRA is dispensed in a carton containing two alcohol preps and two dose trays. Each dose tray consists of a single-dose, 1-mL prefilled glass syringe with a fixed 27 gauge ½ inch needle, providing 40 mg (0.8 mL) of HUMIRA.

HUMIRA continues to be available in prefilled syringes.

A patient may self-inject HUMIRA if a physician determines that it is appropriate and with medical follow-up, as necessary, after proper training in subcutaneous injection technique.

Anaphylaxis or serious allergic reactions may occur.

In placebo-controlled trials, 20% of HUMIRA-treated patients developed injection site reactions, compared to 14% of patients receiving placebo. Most reactions were mild and generally did not necessitate discontinuation.



HUMIRA[®] adalimumab

Patients treated with HUMIRA have an increased risk of serious infections leading to hospitalizations or death, including TB, bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.

Please see Important Safety Information, including **BOXED WARNING** on Risk of Serious Infections, on next page.

Please visit www.HUMIRA.com or call Abbott Medical Information at 1-800-633-9110 for full Prescribing Information.

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IMPORTANT SAFETY INFORMATION¹

Risk of Serious Infections

Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. HUMIRA should be discontinued if a patient develops a serious infection or sepsis. Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before HUMIRA use and during therapy. Treatment for latent infection should be initiated prior to HUMIRA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral and other infections due to opportunistic pathogens.**

The risks and benefits of treatment with HUMIRA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with HUMIRA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Serious and sometimes fatal infections have been reported with the use of TNF-blocking agents. Do not start HUMIRA in patients with an active infection, including localized infections. Exercise caution in patients with chronic or recurrent infection or with underlying conditions which may predispose them to infection, patients who have been exposed to TB, or patients who have resided or traveled in regions where TB or mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, are endemic. Treatment of latent TB infection prior to therapy with TNF-blocking agents has been shown to reduce the risk of TB reactivation during therapy. When TB skin testing is performed, an induration size of 5mm or greater should be considered positive, even if vaccinated previously with Bacille Calmette-Guerin (BCG). HUMIRA should be discontinued if a patient develops a serious infection or sepsis. Patients who develop a new infection should undergo a prompt and complete diagnostic workup and appropriate antimicrobial therapy should be initiated.

Malignancies

More cases of malignancies have been observed among patients receiving TNF blockers, including HUMIRA, compared to control patients in clinical trials. These malignancies, other than lymphoma and non-melanoma skin cancer, were similar in type and number to what would be expected in the general population. In the controlled and open-label portions of HUMIRA clinical trials, there was an approximately 3-fold higher rate of lymphoma than expected in the general population. The potential role of TNF-blocking therapy in the development of malignancies is not known.

Hypersensitivity

Anaphylaxis and angioneurotic edema have been reported rarely following HUMIRA administration.

Hepatitis B Reactivation

Use of TNF blockers, including HUMIRA, may increase the risk of reactivation of hepatitis B (HBV) in patients who are chronic carriers. Some cases have been fatal. Patients at risk for HBV infection should be evaluated for prior evidence of HBV infection before initiating TNF blocker therapy. For patients identified as carriers of HBV, exercise caution when prescribing HUMIRA, with careful evaluation and monitoring prior to and during treatment. HUMIRA should be stopped and antiviral therapy should be initiated in patients who develop hepatitis B reactivation.

Neurologic Reactions

TNF-blocking agents, including HUMIRA, have been associated in rare cases with new onset or exacerbation of demyelinating disease. Exercise caution when considering HUMIRA for patients with these disorders.

Hematologic Reactions

Rare reports of pancytopenia including aplastic anemia have been reported with TNF-blocking agents. Medically significant cytopenia (e.g. thrombocytopenia, leukopenia) has been infrequently reported with HUMIRA. The causal relationship of these reports to HUMIRA remains unclear.

Congestive Heart Failure

Worsening congestive heart failure (CHF) has been observed with TNF-blocking agents, including HUMIRA, and new onset CHF has been reported with TNF-blocking agents.

Autoimmunity

Treatment with HUMIRA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of lupus-like syndrome develop.

Immunizations

Patients on HUMIRA should not receive live vaccines. It is recommended that juvenile idiopathic arthritis patients, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating HUMIRA therapy.

Drug Interactions

Serious infections were seen in studies with concurrent use of anakinra and another TNF-blocking agent, therefore, the combination of HUMIRA and anakinra is not recommended.

Adverse Reactions

In the placebo-controlled clinical studies of adult patients with rheumatoid arthritis the most frequent adverse reactions vs placebo were injection site reactions (20% vs 14%), upper respiratory infection (17% vs 13%), injection site pain (12% vs 12%), headache (12% vs 8%), rash (12% vs 6%), and sinusitis (11% vs 9%). Discontinuations due to adverse events were 7% for HUMIRA vs 4% for placebo.

In HUMIRA clinical trials for ankylosing spondylitis, psoriatic arthritis, Crohn's disease, and plaque psoriasis, the safety profile for patients treated with HUMIRA was similar to the safety profile seen in patients with rheumatoid arthritis. In the placebo-controlled clinical trials in plaque psoriasis, the incidence of arthralgia was 3% in HUMIRA-treated patients versus 1% in controls.

In general, the adverse reactions in juvenile idiopathic arthritis (JIA) patients were similar in frequency and type to those seen in adult patients. Severe adverse reactions reported in the clinical trial in JIA included neutropenia, streptococcal pharyngitis, increased aminotransferases, herpes zoster, myositis, metrorrhagia, and appendicitis. Serious infections were observed in 4% of patients within approximately 2 years of initiation of treatment with HUMIRA and included cases of herpes simplex, pneumonia, urinary tract infection, pharyngitis, and herpes zoster. The safety of HUMIRA in pediatric patients for uses other than JIA has not been established.

Reference: 1. HUMIRA Injection [package insert]. North Chicago, IL: Abbott Laboratories.

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