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Important Information

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HUMIRA is indicated for reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). HUMIRA can be used alone or in combination with methotrexate (MTX) or other disease-modifying antirheumatic drugs (DMARDs). When used as first-line treatment in recently diagnosed patients who have not been previously treated with MTX, HUMIRA should be given in combination with MTX. HUMIRA can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is contraindicated. HUMIRA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS) who have had an inadequate response to conventional therapy. HUMIRA is indicated for reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis (PsA) patients. HUMIRA can be used in combination with MTX in patients who do not respond adequately to MTX alone.

The most frequently reported adverse events in RA clinical trials were: nausea (6.4%), headache (6.0%), and injection site irritation (5.9%).

The most frequently reported adverse events in AS clinical trials were: headache (4.5%), nasopharyngitis (3.3%), and injection site reaction (3.3%).

The most frequently reported adverse events in PsA clinical trials were: injection site reaction (5.4%), injection site pain (4.0%), and upper respiratory infection (4.0%).

HUMIRA is contraindicated in patients with severe infections such as sepsis, tuberculosis and opportunistic infections.

Very rare post-marketing reports of hepatosplenic T-cell lymphoma (HSTCL), a rare aggressive lymphoma that is often fatal, have been identified in patients treated with HUMIRA (adalimumab). Most of the patients had prior infliximab therapy as well as concomitant azathioprine or 6-mercaptopurine use for Crohn's disease. The causal association of HSTCL with HUMIRA is not clear. Serious infections due to bacterial, mycobacterial, invasive fungal (disseminated or extrapulmonary histoplasmosis, aspergillosis, coccidioidomycosis), viral, parasitic, or other opportunistic infections have been reported in patients receiving tumour necrosis factor (TNF)-blocking agents. Sepsis, rare cases of tuberculosis, candidiasis, listeriosis, and pneumocystis have also been reported with the use of TNF-blocking agents, including HUMIRA. Other serious infections seen in clinical trials include pneumonia, pyelonephritis, septic arthritis and septicemia. Hospitalization or fatal outcomes associated with infections have been reported. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infections. Treatment with HUMIRA should not be initiated in patients with active infections, including chronic or localized infections, until infections are controlled. In patients who have been exposed to tuberculosis, and patients who have travelled in areas of high risk of tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, the risk and benefits of treatment with HUMIRA should be considered prior to initiating therapy. As with other TNF blockers, patients should be monitored closely for infections (including tuberculosis) before, during and after treatment with HUMIRA. Patients whodevelop a new infection while undergoing treatment with HUMIRA should be monitored closely and undergo a complete diagnostic evaluation. Administration of HUMIRA should be discontinued if a patient develops a serious infection or sepsis, and appropriate antimicrobial or antifungal therapy should be initiated. Physicians should exercise caution when considering the use of HUMIRA in patients with a history of recurrent infection or with underlying conditions which may predispose them to infections, or patients who have resided in regions where tuberculosis and histoplasmosis are endemic. The benefits and risks of treatment with HUMIRA

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