ADALIMUMAB (HUMIRA®) - Prescribing Information

DESCRIPTION

HUMIRA® (adalimumab) is a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor (TNF). Adalimumab is produced by recombinant DNA technology in a mammalian cell expression system and is purified by a process that includes specific viral inactivation and removal steps.

INDICATIONS AND USAGE

HUMIRA is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. HUMIRA can be used alone or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).

DOSAGE AND ADMINISTRATION

The recommended dose of HUMIRA for adult patients with rheumatoid arthritis is 40 mg administered every other week by subcutaneous injection. Methotrexate should be continued during treatment with HUMIRA.

CONTRAINDICATIONS

HUMIRA is contraindicated in patients with known hypersensitivity to adalimumab or any of its components. HUMIRA should not be given concurrently with live vaccines. HUMIRA is contraindicated in patients with an active infection.

WARNINGS AND PRECAUTIONS

Increased risk of serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Lymphoma and other malignancies have been reported in patients treated with TNF blockers.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) in HUMIRA clinical trials were: injection site reactions, upper respiratory infections, headache, and rash. Serious adverse reactions include serious infections, neurological events, and hematological events.

DRUG INTERACTIONS

Live vaccines should not be given concurrently with HUMIRA. No data are available on the secondary transmission of infection by live vaccines in patients receiving HUMIRA. Concomitant use of HUMIRA with other biologic DMARDs or targeted synthetic DMARDs is not recommended.