adalimumab (a-da-lio-mab)

Humira

Classification
Therapeutic: antirheumatics
Pharmacologic: DMARDs, monoclonal antibodies

Pregnancy Category: B

Indications
Moderately to severely active rheumatoid arthritis (may be used alone or with methotrexate or other DMARDs). Active ankylosing spondylitis. Moderate to severely active Crohn’s disease in patients who have responded inadequately to conventional therapy. Moderately to severely active ulcerative colitis in patients who have responded inadequately to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine. Moderate to severely active plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are deemed inappropriate.

Action
Neutralizes and prevents the action of tumor necrosis factor (TNF), resulting in anti-inflammatory and antiproliferative activity.

Therapeutic Effects:
Decreased pain and swelling with decreased rate of joint destruction in patients with rheumatoid arthritis, psoriatic arthritis, juvenile arthritis, and ankylosing spondylitis. Reduced signs and symptoms and maintenance of clinical remission of Crohn’s disease. Induction and maintenance of clinical remission of ulcerative colitis. Reduced severity of plaques.

Pharmacokinetics
Absorption: 64% absorbed after subcut administration.
Distribution: Synovial fluid concentrations are 31–96% of serum.
Metabolism and Excretion: Unknown.
Half-life: 14 days (range 10–20 days).

Contraindications/Precautions
Contraindicated in:
Hypersensitivity; Concurrent use of anakinra or abatacept; Active infection (including localized); Lactation: Potential for serious side effects in the infant; discontinue drug or provide formula.

Use Cautiously in:
History of chronic or recurrent infection or underlying illness/treatment predisposing to infection; History of opportunistic infection; Patients residing, or who have resided, where tuberculosis, histoplasmosis, coccidioidomycoses, or blastomycosis is endemic; Patients residing, or who have resided, where tuberculosis, histoplasmosis, coccidioidomycoses, or blastomycosis is endemic; History of lymphoma; Geri: increased risk of infection/malignancy; OB: Use only if clearly needed; Pedi: Children <4 yr (safety not established); q risk of lymphoma (including hepatosplenic T-cell lymphoma [HSTCL] in patients with Crohn’s disease or ulcerative colitis), leukemia, and other malignancies.

Adverse Reactions/Side Effects
CNS:
headache, Guillain-Barre syndrome, multiple sclerosis, CV:
hypertension.
EENT:
opptic neuritis.
GI:
abdominal pain, nausea.
GU:
hematuria.
Derm:
rash, psoriasis.
Hemat:
neutropenia, thrombocytopenia.
Local:
injection site reactions.
Metab:
hypercholesterolemia, hyperlipidemia.
MS:
back pain.
Misc:
allergic reactions including ANAPHYLAXIS, ANGIOEDEMA, INFECTIONS (including reactivation tuberculosis and other opportunistic infections due to bacterial, invasive fungal, viral, mycobacterial, and parasitic pathogens), neoplasms (including lymphoma, HSTCL, leukemia, and skin cancer), fever.

Interactions
Drug-Drug:
Concurrent use with anakinra, abatacept, or other TNF blocking agents q risk of serious infection and/or lymphoma. Concurrent use with methotrexate may q risk of HSTCL. Live vaccinations should not be given concurrently.
Route/Dosage
Rheumatoid Arthritis, Ankylosing Spondylitis, and Psoriatic Arthritis
Subcut (Adults): 40 mg every other week; patients not receiving concurrent methotrexate may receive additional benefit by increasing dose to 40 mg once weekly.

Crohn’s Disease or Ulcerative Colitis
Subcut (Adults): 160 mg initially on Day 1 (given as four 40-mg injections in one day or as two 40-mg injections given in two consecutive days), followed by 80 mg 2 wk later on Day 15. Two wk later (Day 29), begin maintenance dose of 40 mg every other wk. Aminosalicylates, corticosteroids, and/or immunomodulatory agents (e.g., azathioprine, 6-mercaptopurine, methotrexate) may be continued during therapy.

Juvenile Idiopathic Arthritis
Subcut (Children 6–17 yr): 0.3 mg/kg—30 mg every other wk; 0.5 mg/kg—40 mg every other wk.

Plaque Psoriasis
Subcut (Adults): 80 mg initially, then in 1 wk, begin regimen of 40 mg every other wk.

NURSING IMPLICATIONS
Assessment
- Assess for signs of infection (fever, dyspnea, flu-like symptoms, frequent or painful urination, redness or swelling at the site of a wound), including tuberculous and hepatitis B virus (HBV), prior to and periodically during therapy. New infections should be monitored closely; most common are upper respiratory tract infections, bronchitis, and urinary tract infections. Infections may be fatal, especially in patients taking immunosuppressive therapy.
- Monitor for injection site reactions (redness and/or itching, rash, hives, hives, burning, pain, or swelling). Rash will usually disappear within a few days. Application of a cool, wet cloth or cold water may relieve pain or swelling.
- Assess patient for latex allergy. Needle cover of syringe contains latex and should not be handled by persons sensitive to latex.
- Monitor for signs and symptoms of systemic fungal infections (fever, malaise, weight loss, sweats, cough, dyspnea, pulmonary infiltrates, serious systemic illness with or without concomitant shock). Ascertain if patient lives in or has traveled to areas of endemic mycoses. Consider empiric antifungal treatment for patients at risk of histoplasmosis and other invasive fungal infections until the pathogens are identified. Consult with an infectious diseases specialist. Consider stopping adalimumab until the infection has been diagnosed and adequately treated.

Implementation
- Administer a tuberculin skin test prior to administration of adalimumab. Patients with active latent TB should be treated for TB prior to therapy.
adalimumab

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- Immunizations should be current prior to initiating therapy. Patients on adalimumab may receive concurrent vaccinations, except for live vaccines.
- Administer initial injection under supervision of a health care professional.
- Vial is for institutional use only. With training, patients may use pen and pre-filled syringes at home.
- Do not administer solutions that are discolored or contain particulate matter. Discard unused solution.
- Other DMARDs should be continued during adalimumab therapy.
- Subcut: Administer at a 45° angle in upper thighs or abdomen, avoiding the 2 inches around the navel. Put pressure on injection site for 10 sec, do not rub. Rotate injection sites; avoid areas that are tender, bruised, hard, or red. Refrigerate prefilled syringes and pens.

**Patient/Family Teaching**

- Instruct patient on the correct technique for administering adalimumab. Review Medication Guide; preparation of dose, administration sites and technique, and disposal of equipment into a puncture-resistant container.
- Advise patient to use calendar stickers provided by manufacturer to assist in remembering when dose is due. If dose is missed, instruct patient in administrator as soon as possible; then take next dose according to regular schedule. If more than prescribed dose is taken, instruct patient to contact health care professional or the HUMIRA Patient Resource Center at 1-800-4HUMIRA (448-6472).
- Caution patient to notify health care professional of medication regimen prior to treatment or surgery.
- Advise female patients to notify health care professional if pregnancy is planned or suspected or if breast feeding. Encourage patient to contact the pregnancy registry by calling 1-877-311-8972 (Pregnacare).