ADALIMUMAB

CLASS: Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent

INDICATIONS:

Ankylosing spondylitis: Treatment of ankylosing spondylitis (may be used in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDS)

Crohn's disease: Treatment of active Crohn's disease (moderate-to-severe) in patients with inadequate response to conventional treatment, or patients who have lost response to or are intolerant of infliximab

Juvenile idiopathic arthritis: Treatment of active juvenile idiopathic arthritis (moderate-to-severe); may be used alone or in combination with methotrexate

Plaque psoriasis: Treatment of chronic plaque psoriasis (moderate-to-severe) when systemic therapy is required and other agents are less appropriate

Psoriatic arthritis: Treatment of active psoriatic arthritis; may be used alone or in combination with methotrexate or other DMARDs

Rheumatoid arthritis: Treatment of active rheumatoid arthritis (moderate-to-severe); may be used alone or in combination with methotrexate or other DMARDs

Ulcerative colitis: Treatment of active ulcerative colitis (moderate-to-severe) in patients unresponsive to immunosuppressants (Note: Efficacy in patients that are intolerant to or no longer responsive to other TNF blockers has not been established.)

Canadian labeling: Additional use (not in U.S. labeling): Crohn's disease, pediatric: Treatment of adolescents with active Crohn's disease (moderate-to-severe) who have had an inadequate response to conventional treatment and/or other TNF blockers

AVAILABLE DOSAGE FROM THE HOSPITAL:

ADALIMUMAB 40MG / 0.8ML PRE-FILLED SYRING

TRADE NAMES:

DOSAGE:

- **Dosing: Adult**

  Ankylosing spondylitis: SubQ: 40 mg every other week

  Crohn's disease: SubQ:

  Initial: 160 mg (given as 4 injections on day 1 or given as 2 injections daily over 2 consecutive days), then 80 mg 2 weeks later (day 15). Note: 40 mg per injection.

  Maintenance: 40 mg every other week beginning day 29. Note: Some patients may require 40 mg every week as maintenance therapy (Lichtenstein, 2009).

  Plaque psoriasis: SubQ:

  Initial: 80 mg as a single dose

  Maintenance: 40 mg every other week beginning 1 week after initial dose

  Psoriatic arthritis: SubQ: 40 mg every other week

  Rheumatoid arthritis: SubQ: 40 mg every other week; patients not taking methotrexate may increase dose to 40 mg every week

  Ulcerative colitis: SubQ:

  Initial: 160 mg (given as 4 injections on day 1 or given as 2 injections daily over 2 consecutive days), then 80 mg 2 weeks later (day 15). Note: 40 mg per injection.

  Maintenance: 40 mg every other week beginning day 29. Note: Only continue maintenance dose in patients demonstrating clinical remission by 8 weeks (day 57) of therapy.

- **Dosing: Geriatric**
  Refer to adult dosing.

- **Dosing: Renal Impairment**

  No dosage adjustment provided in manufacturer's labeling (has not been studied).

- **Dosing: Hepatic Impairment**

  No dosage adjustment provided in manufacturer's labeling (has not been studied).

COMMON SIDE EFFECT:

>10%:

Central nervous system: Headache (12%)

Dermatologic: Skin rash (6% to 12%)

Hematologic & oncologic: Positive ANA titer (12%)

Immunologic: Antibody development (3% to 26%; significance unknown)

Infection: Serious infection (adults 1.4-6.7 events/100 person years; children 2 events/100 person years [Burmester, 2012])

Local: Injection site reaction (12% to 20%; includes erythema, itching, hemorrhage, pain, swelling)

Neuromuscular & skeletal: Increased creatine phosphokinase (15%)

Respiratory: Upper respiratory tract infection (17%), sinusitis (11%)

PREGNANCY RISK FACTORS: B