INFLIXIMAB

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

INDICATIONS:

Treatment of moderately- to severely-active rheumatoid arthritis (with methotrexate) (to reduce signs/symptoms of active arthritis and inhibit progression of structural damage and improve physical function)

Treatment of moderately- to severely-active Crohn's disease with inadequate response to conventional therapy (to reduce signs/symptoms and induce and maintain clinical remission) or to reduce the number of draining enterocutaneous and rectovaginal fistulas and maintain fistula closure

Treatment of psoriatic arthritis (to reduce signs/symptoms of active arthritis and inhibit progression of structural damage and improve physical function)

Treatment of chronic severe (extensive and/or disabling) plaque psoriasis as an alternative to other systemic therapy

Treatment of active ankylosing spondylitis (to reduce signs/symptoms)

Treatment of moderately- to severely-active ulcerative colitis with inadequate response to conventional therapy (to reduce signs/symptoms and induce and maintain clinical remission, mucosal healing and eliminate corticosteroid use)

AVAILABLE DOSAGE FROM THE HOSPITAL:

INFLIXIMAB 100MG VIAL

DOSAGE:

- **Dosing Adult:**
  Note: Premedication with antihistamines (H1-antagonist +/- H2-antagonist), acetaminophen, and/or corticosteroids may be considered to prevent and/or manage infusion-related reactions:

  Crohn's disease: I.V.: 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter; dose may be increased to 10 mg/kg in patients who respond but then lose their response. If no response by week 14, consider discontinuing therapy.

  Psoriatic arthritis (with or without methotrexate): I.V.: 5 mg/kg at 0,2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter

Rheumatoid arthritis (in combination with methotrexate therapy): I.V. 3 mg/kg at 0, 2, and 6 weeks, followed by 3 mg/kg every 8 weeks thereafter; doses have ranged from 3-10 mg/kg repeated at 4- to 8-week intervals

Ankylosing spondylitis: I.V.: 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 6 weeks thereafter (Canadian labeling recommends every 6-8 weeks thereafter).

Plaque psoriasis: I.V.: 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter.

Ulcerative colitis: I.V.: 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter

Dosage adjustment with heart failure (HF): Weigh risk versus benefits for individual patient:

Moderate-to-severe (NYHA class III or IV): ≤5 mg/kg

- **Dosing: Geriatric**
  Refer to adult dosing
- **Dosing: Renal Impairment**
  No dosage adjustment provided in manufacturer's labeling
- **Dosing: Hepatic Impairment**
  No dosage adjustment provided in manufacturer's labeling

COMMON SIDE EFFECT:

Although profile is similar, frequency of adverse effects may vary with disease state. Except where noted, percentages reported in adults with rheumatoid arthritis:

>10%:

Central nervous system: Headache (18%)

Gastrointestinal: Nausea (21%), diarrhea (12%), abdominal pain (12%, Crohn's 26%)

Hepatic: ALT increased (risk increased with concomitant methotrexate)

Respiratory: Upper respiratory tract infection (32%), sinusitis (14%), cough (12%), pharyngitis (12%)

Miscellaneous: Development of antinuclear antibodies (~50%), infection (36%), infusion reactions (20%; severe <1%), development of antibodies to double-stranded DNA (20%), development of new abscess (Crohn's patients with fistulizing disease:

15%), anti-infliximab antibodies (variable; ~10% to 15% [range: 6% to 61%]; Mayer, 2006)

PREGNANCY RISK FACTORS: B