inFLIXimab (in-flix-i-mab)

Sericology

Therapeutic: antirheumatics (DMARDs), gastrointestinal anti-inflammatories
Pharmacologic: monoclonal antibodies

Pregnancy Category: C

Indications

Active rheumatoid arthritis (moderate to severe, with methotrexate). Active Crohn’s disease (moderate to severe). Active ulcerative colitis (moderate to severe) with inadequate response to conventional therapy, reducing signs and symptoms, and inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use. Plaque psoriasis (chronic severe).

Action

Neutralizes and prevents the activity of tumor necrosis factor-alpha (TNF-alpha), resulting in anti-inflammatory and antiproliferative activity. Therapeutic Effects: Decreased pain and swelling, decreased rate of joint destruction and improved physical function in ankylosing spondylitis, rheumatoid or psoriatic arthritis. Reduction and maintenance of closure of fistulae in Crohn’s disease. Decreased symptoms, maintaining remission and mucosal healing with decreased corticosteroid use in ulcerative colitis. Decrease in induration, scaling and erythema of psoriatic lesions.

Pharmacokinetics

Absorption: IV administration results in complete bioavailability.

Distribution: Predominantly distributed within the vascular compartment.

Metabolism and Excretion: Unknown.

Half-life: 9.5 days.

TIME/ACTION PROFILE (symptoms of Crohn’s disease)

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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<tbody>
<tr>
<td>IV</td>
<td>1–2 wk</td>
<td>unknown</td>
<td>12–48 wk†</td>
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†After infusion.

Contraindications/Precautions

Contraindicated in: Hypersensitivity to infliximab, murine (mouse) proteins, or other components in the formulation. HF; Concurrent anakinra or abatacept; Use only if clearly needed, PO: Children < 6 yr (safety not established); History of chronic or recurrent infection or underlying illness/treatment predisposing to infection; Patients being retreated after 2 yr without treatment; Use only in clearly needed, Ophthalmic: Preparations containing chemicals that may react with inFLIXimab.

Lactation: Lactation.

Use Cautiously in: History of chronic or recurrent infection or underlying illness/treatment predisposing to infection; Patients being retreated after 2 yr without treatment; Patients residing, or who have resided, in areas endemic for tuberculosis, coccidioidomycosis, or blastomycosis; Chronic obstructive pulmonary disease (q risk of malignancy); Pregnancy (category C); Geri: Geriatric patients; Pedi: Use only in clearly needed; OB: Use only in clearly needed, Pedi: Children < 6 yr (safety not established); History of opportunistic infection; Patients residing, or who have resided, in areas endemic for tuberculosis, coccidioidomycosis, or blastomycosis; Chronic obstructive pulmonary disease (q risk of malignancy); Malignancy (including lymphoma, T-cell lymphoma [HSTCL], in patients with Crohn’s disease or ulcerative colitis), leukemia, and other malignancies.

Adverse Reactions/Side Effects


Interactions

Drug-Drug: Concurrent use with anakinra or abatacept (q risk of serious infections [not recommended]). Concurrent use with azathioprine and/or methotrexate (q risk of HSTCL).
**Route/Dosage**

**Rheumatoid Arthritis**
- **IV (Adults):** 3 mg/kg initially, then repeat at 2 and 6 wk after initial infusion, then repeat qy 8 wk; dose may be adjusted in partial responders up to 10 mg/kg or treat-ment only q 4 wk (to be used with methotrexate).

**Crohn’s Disease**
- **IV (Adults):** 5 mg/kg initially, then repeat at 2 and 6 wk after initial infusion, then maintenance dose of 5 mg/kg q 8 wk; dose may be adjustment up to 10 mg/kg in patients who initially respond and then lose their response.
- **IV (Children):** 5 mg/kg initially, then repeat at 2 and 6 wk after initial infusion, then maintenance dose of 5 mg/kg q 8 wk.

**Ankylosing Spondylitis**
- **IV (Adults):** 5 mg/kg initially, then repeat at 2 and 6 wk after initial infusion, then maintenance dose of 5 mg/kg q 8 wk.

**Psoriatic Arthritis**
- **IV (Adults):** 5 mg/kg initially, then repeat at 2 and 6 wk after initial infusion, then maintenance dose of 5 mg/kg q 8 wk (to be used with or without methotrexate).
- **IV (Children):** 5 mg/kg initially, then repeat at 2 and 6 wk after initial infusion, then maintenance dose of 5 mg/kg q 8 wk.

**NURSING IMPLICATIONS**

**Assessment**
- Assess for infusion-related reactions (fever, chills, urticaria, pruritus) during and for 2 hr after infusion. Symptoms usually resolve when infusion is discontinued. Reactions are more common after 1st or 2nd infusion. Frequency of reactions may be reduced with immunosuppressant agents.
- Monitor patients who develop a new infection while taking infliximab closely. Discontinue therapy in patients who develop a serious infection or sepsis. Do not initiate therapy in patients with active infections.
- Assess for signs and symptoms of systemic infections (fever, malaise, weight loss, sweats, cough, dyspnea, pulmonary infiltrates, serious systemic illness with or without concomitant shock). Incorrect 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 infliximab until the infection has been diagnosed and adequately treated.
- Assess for latent infections with a tuberculin skin test prior to initiation of therapy. Treatment of latent tuberculosis should be initiated prior to therapy with infliximab.
- Observe patient for hyperventilation reactions (urticaria, dyspnea, hypotension) during infusion. Discontinue infusion if severe reaction occurs. Start medi-cations (aminophylline, antihistamines, corticosteroids, sympathomimetics) and equip-ment readily available in the event of an acute reaction.
- **Rheumatoid Arthritis:** Assess pain and range of motion prior to and periodically during therapy.
- **Crohn’s Disease and Ulcerative Colitis:** Assess signs and symptoms before, during, and after therapy.
- **Psoriasis:** Assess lesions periodically during therapy.

**Lab Test Considerations**
- May cause q in positive ANA. Frequency may be decreased with baseline immunosuppressant therapy.
- Monitor liver function tests periodically during therapy. May cause mild to moderate AST and ALT without progressing to liver dysfunction. If patient develops jaundice or liver enzyme elevations 5 times the upper limits of normal, discontinue infliximab.
- Monitor CBC with differential periodically during therapy. May cause leukopenia, neutropenia, thrombocytopenia, and pancytopenia. Discontinue infliximab if symptoms of blood dyscrasias (persistent fever) occur.

**Potential Nursing Diagnoses**
- Chronic pain (Indications)
- Diarrhea (Indications)
- Imbalanced Nutrition: More than body requirements

**Implementation**
- Do not confuse infliximab with etanercept.
inFLIXimab

Continued

**IV Administration**

- **Intermittent Infusion:** Calculate the total number of vials needed. Reconstitute each vial with 10 mL of sterile water for injection using a syringe with a 21 gauge needle or smaller. Direct stream to sides of vial. Do not use if vacuum is not present in vial. Gently swirl solution by inverting vial to dilute; do not shake. Mix slowly on reconstitution, allow to stand for 5 min. Solutions in colorless to light yellow and transparent; a few translucent particles may develop because infliximab is a protein. Do not use if opaque particles, discoloration, or other particles occur.

- **Diluent:** Withdraw volume of total infliximab dose from infusion container containing 250 mL with 0.9% NaCl. Slowly add total dose of infliximab. Concentration: 0.4 to 4 mg/mL. Mix gently. Infusion should begin within 3 hr of preparation. Solution is incompatible with polyvinyl chloride equipment. Prepare in either infusion bottle or polypropylene or polyolefin bags. Do not reuse or store any portion of infusion solution. Rate: Administer over at least 2 hr through polyethylene-lined administration set with an in-line, sterile, nonpyrogenic, low protein-building filter with ≥1.2-micron pore size.

- **Y-Site Incompatibility:** Do not administer concurrently in the same line with any other agents.

**Patient/Family Teaching**

- Advise patient that adverse reactions (myalgia, rash, fever, polyarthralgia, pruritus) may occur 3–12 days after delayed (≥2 yr) retreatment with infliximab. Symptoms usually decrease or resolve within 1–3 days. Instruct patient to notify health care professional if symptoms of fungal infection occur.

- May cause dizziness. Caution patient to avoid driving or other activities requiring alertness until response to medication is known.

- Advise patient to notify health care professional promptly if symptoms of hepatosplenic T-cell lymphoma. Instruct patient to report signs and symptoms (splenomegaly, hepatomegaly, abdominal pain, persistent fever, night sweats, weight loss) to health care professional promptly.

**Evaluation/Desired Outcomes**

- Decreased pain and swelling with decreased rate of joint destruction and improved physical function in patients with ankylosing spondylitis, psoriatic, or rheumatoid arthritis.

- Decrease in the signs and symptoms of Crohn’s disease and a decrease in the number of draining entero-cutaneous fistulas. Decreased symptoms, maintaining remission and mucosal healing with decreased corticosteroid use in ulcerative colitis.

- Decrease in induration, scaling and erythema of psoriatic lesions.

*CD* - Generic Implication. *Continued* - Discontinued.