golimumab (go-luh-muh-bab)
Simponi, Simponi Aria

Classification
Therapeutic: antirheumatics
Pharmacologic: DMARDS, monoclonal antibodies, anti-TNF agents

Pregnancy Category B

Indications
Simponi and Simponi Aria: Treatment of moderately to severely active rheumatoid arthritis (with methotrexate).
Simponi: Treatment of active psoriatic arthritis (alone or with methotrexate).
Simponi: Moderately to severely active ulcerative colitis in patients who have demonstrated corticosteroid dependence or have responded inadequately to immunosuppressants such as aminosalicylates, corticosteroids, antibiotics, or ferrous sulfate.

Action
Inhibits binding of TNFα to receptors inhibiting activity and resulting in anti-inflammatory and antiproliferative activity. Therapeutic Effects: Decreased pain and swelling with decreased joint destruction in patients with rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. Induction and maintenance of clinical remission of ulcerative colitis.

Pharmacokinetics
Absorption: Well absorbed following subcutaneous administration. IV administration results in complete bioavailability.
Distribution: Distributed primarily in the circulatory system with limited extravascular distribution.
Metabolism and Excretion: Unknown.
Half-life: 2 wk.

TIME/ACTION PROFILE (improvement)

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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<tbody>
<tr>
<td>Subcut</td>
<td>within 3 mo</td>
<td>2–7 days</td>
<td>unknown</td>
</tr>
<tr>
<td>IV</td>
<td>unknown</td>
<td>unknown</td>
<td>unknown</td>
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Contraindications/Precautions
Contraindicated: Active infections (including localized). Concurrent use of abatacept or anakinra ( ≤ 1 wk of infections). Lactation: Breast-feeding.
Use Cautiously: In: History of chronic or recurrent infection or underlying illness; treatment predisposing to infection. History of exposure to tuberculosis. History of opportunistic infection. Patients residing, or who have resided, where tuberculosis, histoplasmosis, coccidioidomycosis, or blastomycosis is endemic. History of HIV (may worsen). Pre-existing or recently exposed HIV-delineating disorders. History of cytopenias (may worsen). History of psoriasis (may exacerbate). Hepatitis B virus carriers (risk of reactivation).

Adverse Reactions/Side Effects
Endocrine: diabetes.
GI: abdominal pain, diarrhea, nausea, vomiting, ulcerative colitis.
GU: dysuria.
Musculoskeletal: arthropathy, myalgia, arthritis.
Local: injection site reactions.
Neuro: muscle weakness.
Misc: ANAPHYLAXIS, HYPERSENSITIVITY REACTIONS, INFECTIONS (including reactivation tuberculosis and other opportunistic infections due to bacterial, invasive fungal, viral, mycobacterial, and parasitic pathogens), WOODWARD SYNDROME (including lymphoma, HSTCL, leukemia, and skin cancer).

Interactions
Drug-Drug: Abatacept, anakinra, corticosteroids or methotrexate ↑ risk of serious infections; concurrent use with anakinra or abatacept is not recommended. Antibody responses and ↑ risk of adverse reactions with live virus vaccines. Concomitant use with azathioprine and/or methotrexate may ↑ risk of HSTCL. May normalize previously suppressed levels of CYP450 enzymes. Following initiation or discontinuation of golimumab, effects of substrates of this system may be altered and should be monitored, including warfarin, theophylline, and cyclosporine.

Route/Dosage
Rheumatoid Arthritis
Subcut (Adults): 50 mg once monthly.
IV (Adults): 2 mg/kg initially and 4 wk later, then 2 mg/kg every 8 wk.
Psoriatic Arthritis and Ankylosing Spondylitis

Subcut (Adults): 50 mg once monthly.

Ulcerative Colitis

Subcut (Adults): 200 mg initially, then 100 mg 2 wk later, then 100 mg every 4 wk.

NURSING IMPLICATIONS

Assessment

- Assess for signs and symptoms of infection (fever, dyspnea, flu-like symptoms, frequent or painful urination, redness or swelling at the site of a wound) prior to, during, and after therapy. Discontinue therapy if serious or opportunistic infection or sepsis occurs. If new infection develops during therapy, assess patient and institute antimicrobial therapy. Patients who tested negative for latent tuberculosis (TB) prior to therapy may develop TB during therapy. Initiate treatment for latent TB prior to initiating therapy.
- Test for HBV prior to therapy and monitor carriers of HBV for signs of reactivation during and for several months after therapy. If reactivation occurs, discontinue golimumab and institute antiviral therapy.
- Monitor patients with HF for new or worsening symptoms. Discontinue therapy if symptoms occur.
- Assess for exacerbations and new onset psoriasis. Discontinue therapy if these occur.
- Assess patient for latex allergy. Needle cover of syringe contains latex and should not be handled by persons sensitive to latex.
- Assess for signs and symptoms of systemic fungal infections (fever, malaise, weight loss, cough, dyspnea, pulmonary infiltrates, systemic rashes 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 golimumab until the infection has been diagnosed and adequately treated.
- Monitor for HBV blood tests before starting during, and for several months after therapy is completed.

Potential Nursing Diagnoses

Chronic pain (Indications)

Risk for infection (Adverse Reactions)

Implementation

- Administer a tuberculin skin test prior to administration of golimumab. Assess if treatment for latent tuberculosis is needed; an induration of 5 mm or greater is a positive tuberculin skin test, even for patients previously vaccinated with bacille Calmette-Guérin (BCG). Consider anti-tuberculosis therapy prior to therapy in patients with a history of latent or active tuberculosis if an adequate course of treatment cannot be confirmed, and for patients with risk factors for tuberculosis infection.
- Initial injection should be supervised by health care professional.
- Store refrigerated solution; do not freeze. Allow prefilled syringe or auto-injector to sit at room temperature for 30 min prior to injection; do not warm in any other way. Do not shake. Solution is clear to slightly opalescent and colorless to light yellow. Do not administer solutions that are discolored, cloudy, or contain particulate matter. Discard unused solution.
- Subcut: remove the needle cover or autoinjector cap prior to injection. Inject into sites of middle to lower part of abdomen or thigh, or outer area of upper arm. Do not inject in areas where skin is tender, bruised, red, scaly, or hard. Avoid scars or stretch marks. Press a cotton ball or gauze over injection site for 10 seconds; do not rub.
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golimumab

- **Autoinjector:** Press open end of autoinjector against skin at 90° angle. Use free hand to pinch and hold skin at injection site. Press button with fingers or thumb button will stay pressed and does not need to be held. Injection will begin following a loud click. Keep holding the autoinjector against skin until a second loud click is heard (usually 1–6 seconds, but may take up to 15 seconds). Lift autoinjector from skin following second click. Yellow indicator in viewing window indicates autoinjector worked correctly. If yellow does not appear in viewing window call 1-888-457-6399 for help.

- **Prefilled syringe:** Hold body of syringe between thumb and index finger. Do not pull back on plunger at any time. Pinch skin. Using a dart-like motion, insert needle into pinched skin at 45° angle. Inject all medication by pushing plunger until plunger head is between needle guard wings. Take needle out of skin and pull of plunger to allow empty syringe to move up until entire needle is covered by needle guard.

**Patient/Family Teaching**

- **Instruct patient on correct technique for administration. Review patient information sheet, preparation of dose, administration sites and technique, and disposal of equipment into a puncture-resistant container. Allow patient the option to administer medication in a place of their choice.**

- **Advise patient of risks and benefits of golimumab therapy.** Instruct missed doses as soon as remembered, then return to regular schedule. Instruct patient to read Medication Guide before starting therapy and with each refill, new information may be available.

- **Caution patient not to share this medication with others, even with the same symptoms:** May be harmful.

- **Instruct patient to notify health care professional promptly if any signs of infection, including TB, appear:** Measure of other infections such as fever, malaise, weight loss, fatigue, cough, diarrhea, pneumonia, ulcers, or other symptoms of disease with or without a concurrent illness. Notification of HBV (hepatitis B virus), Shaw's syndrome, or other autoimmune diseases. Notify health care professional promptly if symptoms do not improve or if symptoms worsen.

- **Advise patient to notify health care professional of pregnancy is planned or suspected or if breast feeding.**

**Evaluation/Desired Outcomes**

- **Decreased pain and swelling with decreased rate of joint destruction in patients with rheumatoid arthritis.**

- **Decreased signs and symptoms, slowed progression of joint destruction, and improved physical function in patients with psoriatic arthritis.**

- **Reduced signs and symptoms of arthritis and pain in other joints.**

- **Decreased symptoms, maintaining remission and mucosal healing with decreased corticosteroid use in ulcerative colitis.**

**Why was this drug prescribed for your patient?**