HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use IMMGOLIS safely and effectively. See full prescribing information for IMMGOLIS.

IMMGOLIS™ (golimumab-sldi) injection, for subcutaneous use
Initial U.S. Approval: 2026

IMMGOLIS (golimumab-sldi) is a biosimilar* to SIMPONI (golimumab).

WARNING: SERIOUS INFECTIONS and MALIGNANCY
See full prescribing information for complete boxed warning.

- **Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal (such as histoplasmosis), and other opportunistic infections have occurred in patients receiving golimumab products (5.1).**
- **Discontinue IMMGOLIS if a patient develops a serious infection or sepsis (5.1).**
- **Perform test for latent TB; if positive, start treatment for TB prior to starting IMMGOLIS (5.1).**
- **Monitor all patients for active TB during treatment, even if initial latent TB test is negative (5.1).**
- **Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which IMMGOLIS is a member (5.2).**

----------INDICATIONS AND USAGE ----------

IMMGOLIS is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (1.1)
- adult patients with moderately to severely active ulcerative colitis (UC) (1.2)

----------DOSAGE AND ADMINISTRATION----------

- RA: 50 mg administered by subcutaneous injection once a month (2.2)
- UC: The recommended dosage and administration by subcutaneous injection in adults is shown in the table (2.3)

Recommended Dosage			
Patients with UC	Week 0	Week 2	Week 6 and every 4 weeks thereafter
Adult patients	200 mg	100 mg	100 mg

----------DOSAGE FORMS AND STRENGTHS----------

Injection (3):

- 50 mg/0.5 mL in a single-dose prefilled syringe
- 100 mg/mL in a single-dose prefilled syringe

----------CONTRAINDICATIONS----------

- None (4)

----------WARNINGS AND PRECAUTIONS----------

- Serious Infections: Do not start IMMGOLIS during an active infection. If an infection develops, monitor carefully, and stop IMMGOLIS if infection becomes serious (5.1)
- Invasive Fungal Infections: For patients who develop a systemic illness on IMMGOLIS, consider empiric antifungal therapy for those who reside in or travel to regions where mycoses are endemic (5.1)
- Malignancies: Incidence of lymphoma was greater than in the general U.S. population. Cases of other malignancies have been observed among patients receiving TNF blockers (5.2)
- Congestive Heart Failure: Worsening, or new onset, may occur. Stop IMMGOLIS if new or worsening symptoms occur (5.3)
- Demyelinating Disorders: Exacerbation or new onset may occur (5.4)
- Hepatitis B Reactivation: Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop IMMGOLIS and begin anti-viral therapy (5.5)
- Lupus-like Syndrome: Discontinue IMMGOLIS if symptoms develop (5.6)
- Hypersensitivity Reactions: Serious systemic hypersensitivity reactions including anaphylaxis may occur (5.12)

----------ADVERSE REACTIONS----------

Most common adverse reactions in adults (incidence > 5%) are upper respiratory tract infection, nasopharyngitis, injection site reactions (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Accord BioPharma, Inc. at 1-866-941-7875 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------

- Abatacept: Increased risk of serious infection (5.1, 5.7, 7.2)
- Anakinra: Increased risk of serious infection (5.1, 5.8, 7.2)
- Live vaccines/therapeutic infectious agents: Avoid use with IMMGOLIS (5.10, 7.3).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of IMMGOLIS has been demonstrated for the condition(s) of use (e.g. indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Revised: 05/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

SERIOUS INFECTIONS

Patients treated with golimumab products are at increased risk for developing serious infections that may lead to hospitalization or death *[see Warnings and Precautions (5.1)]*. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue IMMGOLIS if a patient develops a serious infection.

Reported infections with TNF blockers, of which IMMGOLIS is a member, include:

- **Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before IMMGOLIS use and during therapy. Initiate treatment for latent TB prior to IMMGOLIS use.**

- **Invasive fungal infections including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric antifungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**

- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Consider the risks and benefits of treatment with IMMGOLIS prior to initiating therapy in patients with chronic or recurrent infection.

Monitor patients closely for the development of signs and symptoms of infection during and after treatment with IMMGOLIS, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy *[see Warnings and Precautions (5.1)]*.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF-blockers, of which IMMGOLIS is a member *[see Warnings and Precautions (5.2)]*.

1 INDICATIONS AND USAGE

1.1 Rheumatoid Arthritis

IMMGOLIS, in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

1.2 Ulcerative Colitis

IMMGOLIS is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Evaluations and Immunizations Before Initiating IMMGOLIS

Prior to initiating treatment with IMMGOLIS:

- Evaluate patients for active tuberculosis and test for latent infection *[see Warnings and Precautions (5.1)]*.
- Test patients for hepatitis B viral infection.
- If possible, complete all age-appropriate vaccinations according to current immunization guidelines *[see Warnings and Precautions (5.11)]*.

2.2 Recommended Dosage for Rheumatoid Arthritis

The recommended IMMGOLIS dosage in adults is 50 mg administered by subcutaneous injection once a month.

For patients with rheumatoid arthritis (RA), IMMGOLIS should be given in combination with methotrexate. For patients with RA, corticosteroids, non-biologic DMARDs, and/or NSAIDs may be continued during treatment with IMMGOLIS.

2.3 Recommended Dosage for Moderately to Severely Active Ulcerative Colitis in Adults

The recommended dosage is shown in Table 1.

Table 1: Recommended Subcutaneous Dosage for Adult Patients with Moderately to Severely Active Ulcerative Colitis

Patients with UC	Recommended Dosage of IMMGOLIS		
	Week 0	Week 2	Week 6 and every 4 weeks thereafter
Adult patients	200 mg	100 mg	100 mg

2.4 Preparation and Administration Instructions

IMMGOLIS is intended for use under the guidance and supervision of a healthcare provider after proper training in subcutaneous injection technique. Patients may self-inject with IMMGOLIS if a physician determines that it is appropriate. Instruct patients to follow the directions provided in the Instructions for Use.

- To ensure proper use, allow the prefilled syringe to sit at room temperature outside the carton for at least 30 minutes prior to subcutaneous injection. Do not warm IMMGOLIS in any other way.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. IMMGOLIS is clear to slightly opalescent and colorless to light yellow. Do not use IMMGOLIS, if the solution is discolored, or

cloudy, or if foreign particles are present.

- Do not use any leftover product remaining in the prefilled syringe.
- Instruct patients sensitive to latex not to handle the needle cover on the prefilled syringe because it contains dry natural rubber (a derivative of latex).
- At the time of dosing, if multiple injections are required, administer the injections at different sites on the body.
- Rotate injection sites and never give injections into areas where the skin is tender, bruised, red, or hard.
- If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time.

3 DOSAGE FORMS AND STRENGTHS

Injection: 50 mg/0.5 mL and 100 mg/mL clear to slightly opalescent, colorless to light yellow solution in a single-dose prefilled syringe.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Infections

Patients treated with golimumab products are at increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death.

Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, or parasitic organisms including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis, and tuberculosis have been reported with TNF-blockers. Patients have frequently presented with disseminated rather than localized disease. The concomitant use of a TNF-blocker and abatacept or anakinra was associated with a higher risk of serious infections; therefore, the concomitant use of IMMGOLIS and these biologic products is not recommended *[see Warnings and Precautions (5.6, 5.7) and Drug Interactions (7.2)]*.

Treatment with IMMGOLIS should not be initiated in patients with an active infection, including clinically important localized infections. Patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants such as corticosteroids or methotrexate may be at greater risk of infection. Consider the risks and benefits of treatment prior to initiating IMMGOLIS in patients:

- with chronic or recurrent infection;
- who have been exposed to tuberculosis;
- with a history of an opportunistic infection;
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis; or
- with underlying conditions that may predispose them to infection.

Monitoring

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with IMMGOLIS. Discontinue IMMGOLIS if a patient develops a serious infection, an

opportunistic infection, or sepsis. For a patient who develops a new infection during treatment with IMMGOLIS, perform a prompt and complete diagnostic workup appropriate for an immunocompromised patient, initiate appropriate antimicrobial therapy, and closely monitor them.

Serious Infection in Clinical Trials

In controlled Phase 3 trials through Week 16 in patients with RA and other indications serious infections were observed in 1.4% of golimumab-treated patients and 1.3% of control-treated patients. In the controlled Phase 3 trials through Week 16 in patients with RA and other indications the incidence of serious infections per 100 patient-years of follow-up was 5.7 (95% CI: 3.8, 8.2) for the golimumab group and 4.2 (95% CI: 1.8, 8.2) for the placebo group. In the controlled Phase 2/3 trial through Week 6 of golimumab induction in UC, the incidence of serious infections in golimumab 200/100 mg-treated patients was similar to the incidence of serious infections in placebo-treated patients. Through Week 60, the incidence of serious infections was similar in patients who received golimumab induction and 100 mg during maintenance compared with patients who received golimumab induction and placebo during the maintenance portion of the UC trial. Serious infections observed in golimumab-treated patients included sepsis, pneumonia, cellulitis, abscess, tuberculosis, invasive fungal infections, and hepatitis B infection.

Tuberculosis

Cases of reactivation of tuberculosis or new tuberculosis infections have been observed in patients receiving TNF-blockers, including patients who have previously received treatment for latent or active tuberculosis. Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating IMMGOLIS and periodically during therapy.

Treatment of latent tuberculosis infection prior to therapy with TNF blockers has been shown to reduce the risk of tuberculosis reactivation during therapy. Prior to initiating IMMGOLIS, 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-Guerin (BCG).

Consider anti-tuberculosis therapy prior to initiation of IMMGOLIS in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consultation with a physician with expertise in the treatment of tuberculosis is recommended to aid in the decision whether initiating anti-tuberculosis therapy is appropriate for an individual patient.

Cases of active tuberculosis have occurred in patients treated with golimumab products during and after treatment for latent tuberculosis. Monitor patients for the development of signs and symptoms of tuberculosis including patients who tested negative for latent tuberculosis infection prior to initiating therapy, patients who are on treatment for latent tuberculosis, or patients who were previously treated for tuberculosis infection.

Consider tuberculosis in the differential diagnosis in patients who develop a new infection during IMMGOLIS treatment, especially in patients who have previously or recently traveled to countries with a high prevalence of tuberculosis, or who have had close contact with a person with active tuberculosis.

In the controlled and uncontrolled portions of the Phase 2 RA and Phase 3 RA and other indications trials, the incidence of active TB was 0.23 and 0 per 100 patient-years in 2347 golimumab-treated patients and 674 placebo-treated patients, respectively. Cases of TB included pulmonary and extrapulmonary TB. The overwhelming majority of the TB cases occurred in countries with a high incidence rate of TB. In the controlled Phase 2/3 trial of golimumab induction through Week 6 in UC, no cases of TB were observed in golimumab 200/100 mg-treated patients or in placebo-treated

patients. Through Week 60, the incidence per 100 patient-years of TB in patients who received golimumab induction and 100 mg during the maintenance portion of the UC trial was 0.52 (95% CI: 0.11, 1.53). One case of TB was observed in the placebo maintenance group in a patient who received golimumab intravenous (IV) induction.

Invasive Fungal Infections

If patients develop a serious systemic illness and they reside or travel in regions where mycoses are endemic, consider invasive fungal infection in the differential diagnosis. Consider appropriate empiric antifungal therapy and take into account both the risk for severe fungal infection and the risks of antifungal therapy while a diagnostic workup is being performed. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. To aid in the management of such patients, consider consultation with a physician with expertise in the diagnosis and treatment of invasive fungal infections.

5.2 Malignancies

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤ 18 years of age), of which IMMGOLIS is a member. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression, and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months (range 1 to 84 months) after the first dose of TNF-blocker therapy. Most of the patients were receiving concomitant immunosuppressants. These cases were reported postmarketing and are derived from a variety of sources, including registries and spontaneous postmarketing reports.

The risks and benefits of TNF-blocker treatment including IMMGOLIS, should be considered prior to initiating therapy in patients with a known malignancy other than a successfully treated nonmelanoma skin cancer (NMSC) or when considering continuing a TNF-blocker in patients who develop a malignancy.

In the controlled portions of clinical trials of TNF blockers, including golimumab, more cases of lymphoma have been observed among patients receiving anti-TNF treatment compared with patients in the control groups. During the controlled portions of the Phase 2 trials in RA, and the Phase 3 trials in RA and other indications, the incidence of lymphoma per 100 patient-years of follow-up was 0.21 (95% CI: 0.03, 0.77) in the combined golimumab group compared with an incidence of 0 (95% CI: 0, 0.96) in the placebo group. In the controlled and uncontrolled portions of these clinical trials in 2347 golimumab-treated patients with a median follow-up of 1.4 years, the incidence of lymphoma was 3.8-fold higher than expected in the general U.S. population according to the 1964-2004 data from SEER database (adjusted for age, gender, and race).[1] Through Week 60 of the UC trials, there were no cases of lymphoma with golimumab. Patients with RA and other chronic inflammatory diseases, particularly patients with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk (up to several fold) than the general population for the development of lymphoma, even in the absence of TNF-blocking therapy. Cases of acute and chronic leukemia have been reported with TNF-blocker use, including golimumab products, in rheumatoid arthritis and other indications. Even in the absence of TNF-blocker therapy, patients with rheumatoid arthritis may be at a higher risk (approximately 2-fold) than the general population for the development of leukemia.

Rare postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF-blocking agents. This rare type of T-cell lymphoma has a very aggressive disease course and is usually fatal. Nearly all of the reported TNF blocker associated cases have occurred in

patients with Crohn's disease or ulcerative colitis. The majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine (AZA) or 6-mercaptopurine (6–MP) concomitantly with a TNF blocker at or prior to diagnosis. The potential risk with the combination of AZA or 6-MP and golimumab should be carefully considered. A risk for the development for hepatosplenic T-cell lymphoma in patients treated with TNF blockers cannot be excluded.

During the controlled portions of the Phase 2 trial in RA, and the Phase 3 trials in RA and other indications, the incidence of malignancies other than lymphoma per 100 patient-years of follow-up was not elevated in the combined golimumab group compared with the placebo group. In the controlled and uncontrolled portions of these trials, the incidence of malignancies, other than lymphoma, in golimumab-treated patients was similar to that expected in the general U.S. population according to the 1969-2004 SEER database (adjusted for age, gender, and race).[1] In the 6-week placebo-controlled portions of the golimumab Phase 2/3 clinical trials in UC, the incidence of non-lymphoma malignancies (excluding nonmelanoma skin cancer) was similar between the golimumab and the placebo group. Through Week 60, the incidence of non-lymphoma malignancies (excluding nonmelanoma skin cancer) was similar to the general U.S. population according to the 1969-2004 SEER database (adjusted for age, gender, and race).[1] Short follow-up periods, such as those of one year or less in the studies above, may not adequately reflect the true incidence of malignancies.

It is not known if golimumab product treatment influences the risk for developing dysplasia or colon cancer. All patients with ulcerative colitis who are at increased risk for dysplasia or colon carcinoma (for example, patients with long-standing ulcerative colitis or primary sclerosing cholangitis), or who had a prior history of dysplasia or colon carcinoma should be screened for dysplasia at regular intervals before therapy and throughout their disease course. This evaluation should include colonoscopy and biopsies per local recommendations. In patients with newly diagnosed dysplasia treated with IMMGOLIS, the risks and benefits to the individual patient must be carefully reviewed and consideration should be given to whether therapy should be continued.

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocking agents, including golimumab products. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

In controlled trials of other TNF blockers in patients at higher risk for malignancies (e.g., patients with chronic obstructive pulmonary disease [COPD], patients with Wegener's granulomatosis treated with concomitant cyclophosphamide) a greater portion of malignancies occurred in the TNF-blocker group compared to the controlled group. In an exploratory 1-year clinical trial evaluating the use of 50 mg, 100 mg, and 200 mg of golimumab in 309 patients with severe persistent asthma, 6 patients developed malignancies other than NMSC in the golimumab groups compared to none in the control group. Three of the 6 patients were in the 200-mg golimumab group.

5.3 Congestive Heart Failure

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including golimumab products. Some cases had a fatal outcome. In several exploratory trials of other TNF blockers in the treatment of CHF, there were greater proportions of TNF-blocker-treated patients who had CHF exacerbations requiring hospitalization or increased mortality. Golimumab products have not been studied in patients with a history of CHF and IMMGOLIS should be used with caution in patients with CHF. If a decision is made to administer IMMGOLIS to patients with CHF, these patients should be closely monitored during therapy, and IMMGOLIS should be discontinued if new or worsening symptoms of CHF appear.

5.4 Demyelinating Disorders

Use of TNF blockers, of which IMMGOLIS is a member, has been associated with rare cases of new onset or exacerbation of central nervous system (CNS) demyelinating disorders, including multiple sclerosis (MS) and peripheral demyelinating disorders, including Guillain-Barré syndrome. Cases of central demyelination, MS, optic neuritis, and peripheral demyelinating polyneuropathy have rarely been reported in patients treated with golimumab *[see Adverse Reactions (6.1)]*. Prescribers should exercise caution in considering the use of TNF blockers, including IMMGOLIS, in patients with central or peripheral nervous system demyelinating disorders. Discontinuation of IMMGOLIS should be considered if these disorders develop.

5.5 Hepatitis B Virus Reactivation

The use of TNF-blockers including golimumab products has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic hepatitis B carriers (i.e., surface antigen positive). In some instances, HBV reactivation occurring in conjunction with TNF blocker therapy has been fatal. The majority of these reports have occurred in patients who received concomitant immunosuppressants.

All patients should be tested for HBV infection before initiating TNF-blocker therapy. For patients who test positive for hepatitis B surface antigen, consultation with a physician with expertise in the treatment of hepatitis B is recommended before initiating TNF-blocker therapy. The risks and benefits of treatment should be considered prior to prescribing TNF-blockers, including IMMGOLIS, to patients who are carriers of HBV. Adequate data are not available on whether antiviral therapy can reduce the risk of HBV reactivation in HBV carriers who are treated with TNF-blockers. Patients who are carriers of HBV and require treatment with TNF blockers should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy.

In patients who develop HBV reactivation, TNF blockers should be stopped and antiviral therapy with appropriate supportive treatment should be initiated. The safety of resuming TNF blockers after HBV reactivation has been controlled is not known. Therefore, prescribers should exercise caution when considering resumption of TNF blockers in this situation and monitor patients closely.

5.6 Autoimmunity

Treatment with TNF blockers, including IMMGOLIS, may result in the formation of antinuclear antibodies (ANA) and rarely, in the development of a lupus-like syndrome *[see Adverse Reactions (6.1)]*. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with IMMGOLIS, treatment should be discontinued.

5.7 Use with Abatacept

In controlled trials, the concurrent administration of another TNF blocker and abatacept was associated with a greater proportion of serious infections than the use of a TNF blocker alone; and the combination therapy, compared to the use of a TNF blocker alone, has not demonstrated improved clinical benefit in the treatment of RA. Therefore, the combination of TNF blockers, including IMMGOLIS, and abatacept is not recommended *[see Drug Interactions (7.2)]*.

5.8 Use with Anakinra

Concurrent administration of anakinra (an interleukin-1 antagonist) and another TNF blocker was associated with a greater portion of serious infections and neutropenia and no additional benefits compared with the TNF-blocker alone. Therefore, the combination of anakinra with TNF blockers, including IMMGOLIS, is not recommended *[see Drug Interactions (7.2)]*.

5.9 Switching Between Biological Disease Modifying Antirheumatic Drugs

Care should be taken when switching from one biological product to another biologic product since overlapping biological activity may further increase the risk of infection.

5.10 Hematologic Cytopenias

There have been reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anemia, and thrombocytopenia in patients receiving golimumab products. Caution should be exercised when using TNF blockers, including IMMGOLIS, in patients who have or have had significant cytopenias.

5.11 Vaccinations/Therapeutic Infectious Agents

Live Vaccines

Patients treated with IMMGOLIS may receive vaccinations, except for live vaccines. In patients receiving anti-TNF therapy, limited data are available on the response to live vaccination, or on the secondary transmission of infection by live vaccines. Use of live vaccines could result in clinical infections, including disseminated infections.

If possible, it is recommended that prior to initiating therapy with IMMGOLIS, patients be brought up to date with all immunizations in agreement with current immunization guidelines.

Therapeutic Infectious Agents

Other uses of therapeutic infectious agents such as live attenuated bacteria (e.g., BCG bladder instillation for the treatment of cancer) could result in clinical infections, including disseminated infections. It is recommended that therapeutic infectious agents not be given concurrently with IMMGOLIS.

Non-live Vaccines

In the Phase 3 trial for another indication, after pneumococcal vaccination, a similar proportion of golimumab-treated and placebo-treated patients were able to mount an adequate immune response of at least a 2-fold increase in antibody titers to pneumococcal polysaccharide vaccine. In both golimumab-treated and placebo-treated patients, the proportions of patients with response to pneumococcal vaccine were lower among patients receiving MTX compared with patients not receiving MTX. The data suggest that golimumab products do not suppress the humoral immune response to the pneumococcal vaccine.

5.12 Hypersensitivity Reactions

In postmarketing experience, serious systemic hypersensitivity reactions (including anaphylactic reaction) have been reported following golimumab product administration. Some of these reactions occurred after the first administration of golimumab products. If an anaphylactic or other serious allergic reaction occurs, administration of IMMGOLIS should be discontinued immediately and appropriate therapy instituted.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Serious Infections *[see Warnings and Precautions (5.1)]*
- Malignancies *[see Warnings and Precautions (5.2)]*
- Congestive Heart Failure *[see Warnings and Precautions (5.3)]*
- Demyelinating Disorders *[see Warnings and Precautions (5.4)]*

- Hepatitis B Reactivation *[see Warnings and Precautions (5.5)]*
- Autoimmunity *[see Warnings and Precautions (5.6)]*
- Hematologic Cytopenias *[see Warnings and Precautions (5.10)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.12)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety data described below are based on:

- Five pooled, randomized, double-blind, controlled Phase 3 trials in patients with RA and other indications (Trials RA-1, RA-2, RA-3, and other studies) *[see Clinical Studies (14.1)]*. These 5 trials included 639 control-treated patients and 1659 golimumab-treated patients including 1089 with RA, 292 with one indication, and 278 with another indication.
- Three pooled, randomized, double-blind, controlled Phase 2/3 in 1233 golimumab-treated adult patients with UC (Trials UC-1, UC-2, and UC-3 (NCT03596645)) *[see Clinical Studies (14.4)]*.

The proportion of adult patients who discontinued treatment due to adverse reactions in the controlled Phase 3 trials through Week 16 in RA and other indications was 2% for golimumab-treated patients and 3% for placebo-treated patients. The most common adverse reactions leading to discontinuation of golimumab in the controlled Phase 3 trials in RA and other indications through Week 16 were sepsis (0.2%), alanine aminotransferase increased (0.2%), and aspartate aminotransferase increased (0.2%). The most common adverse drug reactions leading to discontinuation through Week 60 of the UC trials in adult patients who received golimumab induction and 100 mg during maintenance compared with patients who received golimumab induction and placebo during maintenance were tuberculosis (0.3% vs. 0.6%) and anemia (0.3% vs. 0%), respectively.

Upper respiratory tract infection and nasopharyngitis were the most common adverse reactions reported in the combined Phase 3 RA and other indications trials in adults through Week 16, occurring in 7% and 6% of golimumab-treated patients as compared with 6% and 5% of control-treated patients, respectively.

Infections

In adult controlled Phase 3 trials through Week 16 in RA and other indications, infections were observed in 28% of golimumab-treated patients compared to 25% of control-treated patients. For serious infections, see the Warnings and Precautions section *[see Warnings and Precautions (5.1)]*. In Trial UC-1, the rates of infections were similar in golimumab 200/100 mg-treated patients and placebo-treated patients, or approximately 12%. Through Week 60, the incidence per patient year of infections was similar in patients who received golimumab induction and 100 mg during maintenance compared with patients who received golimumab induction and placebo during the maintenance period Trial UC-2.

Demyelinating Disorders

In Trial UC-1 of golimumab induction through Week 6, no cases of demyelination were observed in golimumab 200/100 mg-treated patients or placebo-treated patients. Through Week 60 in Trial UC-2, there were no cases of demyelination in the golimumab 100-mg group during maintenance. One case of CNS demyelination was observed in the placebo maintenance group in a patient who received golimumab 400/200 mg during induction.

Liver Enzyme Elevations

There have been reports of severe hepatic reactions including acute liver failure in patients receiving TNF blockers. In adult controlled Phase 3 trials of golimumab in patients with RA and other indications through Week 16, ALT elevations ≥ 5 x ULN occurred in 0.2% of control-treated patients and 0.7% of golimumab-treated patients and ALT elevations ≥ 3 x ULN occurred in 2% of control-treated patients and 2% of golimumab-treated patients. Since many of the patients in the Phase 3 trials for RA and other indications were also taking medications that cause liver enzyme elevations (e.g., NSAIDs, MTX), the relationship between golimumab and liver enzyme elevation is not clear.

In Trials UC-1, UC-2, and UC-3, the incidence of ALT elevations ≥ 5 x ULN was similar in golimumab-treated patients and placebo-treated patients, or approximately 1%, with an average duration of follow-up of 46 weeks and 18 weeks, respectively. ALT elevations ≥ 3 x ULN occurred in 2.0% of golimumab-treated patients compared with 1.5% of placebo-treated patients with an average duration of follow-up of 46 weeks and 18 weeks, respectively.

Autoimmune Disorders and Autoantibodies

In the adult controlled Phase 3 trials in patients with RA and other indications through Week 14, there was no association of golimumab treatment and the development of newly positive anti-dsDNA antibodies. In Phase 3 trials in RA and other indications through 1 year of follow-up, 4.0% of golimumab-treated patients and 2.6% of control patients were newly antinuclear antibody (ANA)-positive (at titers of 1:160 or greater). The frequency of anti-dsDNA antibodies at 1 year of follow-up was uncommon in patients who were anti-dsDNA negative at baseline. Through Week 60 of the UC trials (Trials UC-1, UC-2, and UC-3), 3.5% of patients who received golimumab induction and 100 mg during maintenance were newly ANA-positive (at titers of 1:160 or greater) compared with 3.5% of patients who received golimumab induction and placebo during the maintenance period in Trial UC-2. The frequency of anti-dsDNA antibodies at 1 year of follow-up in patients who were anti-dsDNA negative at baseline was 0.5% in patients receiving golimumab induction and 100 mg during maintenance compared with 0% in patients who received golimumab induction and placebo during maintenance *[see Warnings and Precautions (5.6)]*.

Injection Site Reactions

In adult controlled Phase 3 trials through Week 16 in RA and other indications, 6% of golimumab-treated patients had injection site reactions compared with 2% of control-treated patients. The majority of the injection site reactions were mild and the most frequent manifestation was injection site erythema.

In Trial UC-1, 3.4% of golimumab-treated patients had injection site reactions compared with 1.5% in control-treated patients. The majority of the injection site reactions were mild and moderate and the most frequent manifestation was injection site erythema.

In adult controlled Phase 2 and 3 trials in RA and other indications, no patients treated with golimumab developed anaphylactic reactions.

Other Adverse Reactions

Table 2 summarizes the adverse drug reactions that occurred at a rate of at least 1% in the golimumab ± DMARD group and with a higher incidence than in the placebo ± DMARD group during the controlled period of the 5 pooled Phase 3 trials through Week 16 in adult patients with RA and other indications.

Table 2: Adverse Drug Reactions Reported by ≥ 1% of Golimumab-Treated Patients and with a Higher Incidence Than Placebo-Treated Patients in the Adult Phase 3 Trials of RA and other indications through Week 16[a]

	Golimumab ± DMARDs	Placebo ± DMARDs
Patients treated	1659	639
Adverse Reaction		
Infections and infestations		
Upper respiratory tract infection (nasopharyngitis, pharyngitis, laryngitis, and rhinitis)	16%	13%
Viral infections (such as influenza and herpes)	5%	3%
Bronchitis	2%	1%
Superficial fungal infections	2%	1%
Sinusitis	2%	1%
General disorders and administration site conditions		
Injection site reaction (injection site erythema, urticaria, induration, pain, bruising, pruritus, irritation, paresthesia)	6%	2%
Investigations		
Alanine aminotransferase increased	4%	3%
Aspartate aminotransferase increased	3%	2%
Vascular disorders		
Hypertension	3%	2%
Nervous system disorders		
Dizziness	2%	1%
Paresthesia	2%	1%
Gastrointestinal disorders		
Constipation	1%	<1%

[a] Patients may have taken concomitant MTX, sulfasalazine, hydroxychloroquine, low dose corticosteroids (≤ 10 mg of prednisone/day or equivalent), and/or NSAIDs during the trials).

Less Common Clinical Trial Adverse Drug Reactions

Adverse drug reactions that occurred <1% in adult golimumab-treated patients in the RA and other indications clinical trials that do not appear in the Warnings and Precautions section included the following events listed by system organ class:

Infections and infestations: Septic shock, atypical mycobacterial infection, pyelonephritis, arthritis bacterial, bursitis infective

Neoplasms benign, malignant and unspecified: Leukemia

Skin and subcutaneous tissue disorders: Psoriasis (new onset or worsening, palmar/plantar and pustular), vasculitis (cutaneous)

Vascular disorders: Vasculitis (systemic)

Adults with Ulcerative Colitis

In general, adverse reactions reported in adult patients with UC in Trials UC-1, UC-2, and UC-3 were similar to those reported in clinical trials of patients with RA and other indications.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of golimumab products. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to golimumab product exposure.

Immune system disorders: Serious systemic hypersensitivity reactions (including anaphylactic reaction) *[see Warnings and Precautions (5.12)]*, sarcoidosis

Neoplasms benign, malignant and unspecified: Melanoma, Merkel cell carcinoma *[see Warnings and Precautions (5.2)]*

Respiratory, thoracic and mediastinal disorders: Interstitial lung disease

Skin and subcutaneous tissue disorders: Skin exfoliation, lichenoid reactions, rash, bullous skin reactions

7 DRUG INTERACTIONS

7.1 Methotrexate

For the treatment of RA, IMMGOLIS should be used with methotrexate (MTX) *[see Clinical Studies (14.1)]*.

7.2 Biological Products for RA

An increased risk of serious infections has been seen in clinical RA trials of other TNF blockers used in combination with anakinra or abatacept, with no added benefit; therefore, use of IMMGOLIS with abatacept or anakinra is not recommended *[see Warnings and Precautions (5.7, 5.8)]*. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. The concomitant use of IMMGOLIS with biologics approved to treat RA is not recommended because of the possibility of an increased risk of infection.

7.3 Live Vaccines/Therapeutic Infectious Agents

Live vaccines should not be given concurrently with IMMGOLIS *[see Warnings and Precautions (5.11)]*.

Therapeutic infectious agents should not be given concurrently with IMMGOLIS *[see Warnings and Precautions (5.11)]*.

Infants born to women treated with golimumab products during their pregnancy may be at increased risk of infection for up to 6 months. Administration of live vaccines to infants exposed to IMMGOLIS *in utero* is not recommended for 6 months following the mother's last IMMGOLIS injection during pregnancy *[see Use in Specific Populations (8.1)]*.

7.4 Cytochrome P450 Substrates

The formation of CYP450 enzymes may be suppressed by increased levels of cytokines (e.g., TNFα) during chronic inflammation. Therefore, it is expected that for a molecule that antagonizes cytokine activity, such as golimumab products, the formation of CYP450 enzymes could be normalized. Upon initiation or discontinuation of IMMGOLIS in patients being treated with CYP450 substrates with a narrow therapeutic index, monitoring of the effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) is recommended and the individual dose of the drug product may be adjusted as needed.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from postmarketing case reports with golimumab product use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. An observational study of northern European births observed similar unadjusted rates of major birth defects in infants exposed *in utero* to golimumab products compared to no treatment or non-biologic systemic therapy. However, this study had important limitations *[see Data]*.

Monoclonal antibodies, such as golimumab products, are transported across the placenta during the third trimester of pregnancy and may affect immune response in the *in utero* exposed infant *[see Clinical Considerations]*. In an animal reproductive study, golimumab administered by the subcutaneous route to pregnant monkeys, during the period of organogenesis, at doses that produced exposures approximately 360 times the maximum recommended human dose (MRHD) had no adverse fetal effects *[see Data]*. In a pre- and post-natal development study with pregnant monkeys, subcutaneous administration of golimumab, during the later gestational and lactation periods, at doses producing maximal maternal blood concentrations approximately 460 times those found with the MRHD had no adverse developmental effects on infants *[see Data]*. Data suggest that there are risks to the mother and the fetus associated with rheumatoid arthritis and ulcerative colitis in pregnancy *(see Clinical Considerations)*. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated populations is unknown. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and of miscarriage is 15-20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data suggest that increased disease activity is associated with the risk of developing adverse pregnancy outcomes in women with rheumatoid arthritis or ulcerative colitis. Adverse pregnancy outcomes include preterm delivery (before 37 weeks gestation), low birth weight (less than 2500 g) infants, and small for gestational age at birth.

Fetal/Neonatal Adverse Reactions

Golimumab products cross the placenta during pregnancy. Another TNF-blocking monoclonal antibody administered during pregnancy was detected for up to 6 months in the serum of infants. Consequently, these infants may be at increased risk of infection. Administration of live vaccines to infants exposed to IMMGOLIS *in utero* is not recommended for 6 months following the mother's last IMMGOLIS injection during pregnancy *[see Warnings and Precautions (5.11) and Drug Interactions (7.3)]*.

Data

Human Data

An observational, exposure-based, cohort study based on data from the Swedish, Danish, and Finnish Medical Birth Registers conducted between 2006-2020 (Sweden and Denmark) and 2006-2019 (Finland) compared the risk of major birth defects in 134 live-born infants exposed to golimumab products (116 from women treated for rheumatic conditions, 18 from women treated for ulcerative colitis) to no treatment or nonbiologic systemic therapy. The unadjusted rate of major birth defects in infants exposed *in utero* was similar across all groups. However, this study had important

limitations such as a small number of pregnant women exposed to golimumab products, a wide exposure ascertainment window, and incomplete risk adjustment for potential confounders.

Animal Data

In an embryofetal developmental toxicology study in which pregnant cynomolgus monkeys were treated with golimumab during the period organogenesis from gestation days (GD) 20 to 51, exposures up to 360 times greater than the exposure at the MRHD (on an area under the curve (AUC) basis with maternal subcutaneous doses up to 50 mg/kg twice weekly) produced no evidence of fetal malformations or embryotoxicity. There was no evidence of maternal toxicity. Umbilical cord blood samples collected at the end of the second trimester showed that fetuses were exposed to golimumab during gestation.

In a pre- and postnatal developmental study in which pregnant cynomolgus monkeys were treated with golimumab from gestation day 50 to postpartum day 33, maximal drug concentrations approximately 460 times greater than that found with the MRHD (on a maximum blood concentration (C_{max}) basis at steady-state with maternal subcutaneous doses up to 50 mg/kg twice weekly) were not associated with any evidence of developmental defects in infants. There was no evidence of maternal toxicity. Golimumab was present in fetal serum at the end of the second trimester and in neonatal serum from the time of birth and for up to 6 months postpartum.

8.2 Lactation

Risk Summary

There is no information regarding the presence of golimumab products in human milk, the effects on breastfed infants, or the effects on milk production. Maternal IgG is known to be present in human milk. Golimumab is present in the milk of lactating cynomolgus monkeys *[see Data]*. If golimumab products are transferred into human milk, the effects of local exposure in the gastrointestinal tract and potential limited systemic exposure in the infant to golimumab products are unknown. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for IMMGOLIS and any potential adverse effects on the breast-fed infants from IMMGOLIS, or from the underlying maternal condition.

Data

In the pre- and postnatal development study in cynomolgus monkeys in which golimumab was administered subcutaneously during pregnancy and lactation, golimumab was detected in the breast milk at concentrations that were approximately 400-fold lower than the maternal serum concentrations.

8.4 Pediatric Use

A pediatric assessment for IMMGOLIS demonstrates that IMMGOLIS is safe and effective for pediatric patients in an indication for which Simponi® (golimumab) is approved. However, IMMGOLIS is not approved for such indication due to marketing exclusivity for Simponi® (golimumab).

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

The safety and efficacy of golimumab were evaluated in a multicenter, placebo-controlled, double-blind, randomized-withdrawal, parallel group study in 173 children (2 to 17 years of age) with active polyarticular juvenile idiopathic arthritis (pJIA) despite treatment with MTX for at least 3 months. Subjects were maintained on their stable dose of MTX at the same dose (mg/week) at study entry. Concurrent use of stable doses of oral corticosteroids (≤10 mg/day or 0.2 mg/kg/day prednisone or equivalent, whichever was less) and/or NSAIDs was permitted. In the 16 week open-label phase, all patients received MTX and golimumab 30 mg/m2 (maximum 50 mg) subcutaneously every 4 weeks. Patients who achieved an ACR Ped 30 response at Week 16 entered the randomized-withdrawal phase of the study and received MTX and either golimumab 30 mg/m2 (maximum 50 mg) or placebo every 4 weeks through Week 48.

The primary endpoint of the study was the proportion of patients who did not experience a flare between Week 16 and Week 48, among all subjects who entered the randomized withdrawal phase. The efficacy of golimumab in the treatment of pJIA was not demonstrated in this study because there was no statistical evidence of differences in flare rate between golimumab-treated patients and placebo patients between Weeks 16 and 48.

In this study, the frequency and type of the adverse reactions seen in children were generally similar to those observed in adults.

8.5 Geriatric Use

In the Phase 3 trials in RA and other indications, there were no overall differences in SAEs, serious infections, and AEs in golimumab-treated patients ages 65 or older (N=155) compared with younger golimumab-treated patients. Clinical studies of golimumab in patients with moderately to severely active ulcerative colitis did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger adult patients. Because there is a higher incidence of infections in the geriatric population in general, caution should be used in treating geriatric patients with IMMGOLIS *[see Warnings and Precautions (5.1, 5.5)]*.

11 DESCRIPTION

Golimumab-sldi is a human IgG1κ monoclonal antibody specific for human tumor necrosis factor alpha (TNFα) that exhibits multiple glycoforms with molecular masses of approximately 150 to 151 kilodaltons. Golimumab-sldi was created using recombinant DNA technology, resulting in an antibody with human-derived antibody variable and constant regions. Golimumab-sldi is produced by a Chinese Hamster Ovary (CHO) cell line and is purified by a series of steps that includes measures to inactivate and remove viruses.

IMMGOLIS (golimumab-sldi) injection is a sterile, preservative-free, clear to slightly opalescent, colorless to light yellow solution of the golimumab-sldi antibody supplied in a single-dose prefilled syringe (with a passive needle safety guard).

Each 0.5 mL prefilled syringe contains 50 mg golimumab-sldi, histidine (0.14 mg), L- histidine monohydrochloride monohydrate (0.86 mg), polysorbate 80 (0.10 mg), trehalose (38.453 mg) and

Water for Injection. Each 1 mL prefilled syringe contains 100 mg golimumab-sldi, histidine (0.28 mg), L-histidine monohydrochloride monohydrate (1.72 mg), polysorbate 80 (0.20 mg), trehalose (76.905 mg) and Water for Injection. The pH is approximately 5.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Golimumab products are human monoclonal antibodies that bind to both the soluble and transmembrane bioactive forms of human TNFα. This interaction prevents the binding of TNFα to its receptors, thereby inhibiting the biological activity of TNFα (a cytokine protein). There was no evidence of the golimumab product antibodies binding to other TNF superfamily ligands; in particular, the golimumab product antibodies did not bind or neutralize human lymphotoxin. Golimumab products did not lyse human monocytes expressing transmembrane TNF in the presence of complement or effector cells.

Elevated TNFα levels in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis. TNFα is an important mediator of the articular inflammation that is characteristic of these diseases. The exact mechanism by which golimumab products treat ulcerative colitis is unknown. Golimumab modulated the *in vitro* biological effects mediated by TNF in several bioassays, including the expression of adhesion proteins responsible for leukocyte infiltration (E-selectin, ICAM-1 and VCAM-1) and the secretion of proinflammatory cytokines (IL-6, IL-8, G-CSF and GM-CSF).

12.2 Pharmacodynamics

In clinical trials, decreases in C-reactive protein (CRP), interleukin (IL)-6, matrix metalloproteinase-3 (MMP-3), intercellular adhesion molecule (ICAM)-1 and vascular endothelial growth factor (VEGF) were observed following golimumab administration in patients with RA.

12.3 Pharmacokinetics

Absorption

Following subcutaneous administration of golimumab to healthy subjects and patients with active RA, the median time to reach maximum serum concentrations (T_{max}) ranged from 2 to 6 days. A subcutaneous injection of 50-mg golimumab to healthy subjects produced a mean ± standard deviation maximum serum concentration (C_{max}) of 3.2 ± 1.4 mcg/mL.

By cross-trial comparisons of mean AUC_{inf} values following an IV or subcutaneous administration of golimumab, the absolute bioavailability of subcutaneous golimumab was estimated to be approximately 53%.

Distribution

Following a single IV administration over the dose range of 0.1 to 10.0 mg/kg in patients with active RA, mean volume of distribution ranged from 58 to 126 mL/kg. The volume of distribution for golimumab indicates that golimumab is distributed primarily in the circulatory system with limited extravascular distribution.

Metabolism

The exact metabolic pathway of golimumab products is unknown.

Elimination

Following a single IV administration over the dose range of 0.1 to 10.0 mg/kg in patients with active

RA, mean systemic clearance of golimumab was estimated to be 4.9 to 6.7 mL/day/kg.

Median terminal half-life values were estimated to be approximately 2 weeks in healthy subjects and patients with active RA.

Population PK analyses indicated that concomitant use of NSAIDs, oral corticosteroids, or sulfasalazine did not influence the apparent clearance of golimumab.

Patients who developed anti-golimumab antibodies generally had lower steady-state serum trough concentrations of golimumab.

Dose Linearity

Golimumab exhibited dose-proportional pharmacokinetics (PK) in patients with active RA over the dose range of 0.1 to 10 mg/kg following a single intravenous (IV) dose. Following a single SC dose in healthy subjects, dose proportional pharmacokinetics were also observed over a dose range of 50 mg to 400 mg.

Single Dose Versus Multiple Doses

When 50-mg golimumab was administered subcutaneous to patients with RA every 4 weeks, serum concentrations appeared to reach steady state by Week 12. With concomitant use of methotrexate (MTX), treatment with 50-mg golimumab subcutaneous every 4 weeks resulted in a mean steady-state trough serum concentration of approximately 0.4-0.6 mcg/mL in patients with active RA. Patients with RA treated with golimumab 50 mg and MTX had approximately 52% higher mean steady-state trough concentrations of golimumab, compared with those treated with golimumab 50 mg without MTX. The presence of MTX also decreased anti-golimumab antibody incidence from 7% to 2% *[see Adverse Reactions (6.1)]*. For RA, golimumab should be used with MTX.

When induction doses of 200-mg and 100-mg golimumab at week 0 and 2, respectively, followed by maintenance doses of 100-mg golimumab every 4 weeks were administered subcutaneously in patients with UC, serum golimumab concentrations reached steady-state by week 8 after the first maintenance dose. Treatment with 100-mg golimumab subcutaneous every 4 weeks during maintenance resulted in a mean steady-state trough serum concentration of approximately 1.8 ± 1.1 mcg/mL.

Effect of Weight on Pharmacokinetics in Adults

Higher apparent clearance of golimumab was associated with increasing weight. Treatment with the recommended maintenance dose regimen of golimumab 100 mg in adult patients with UC did not result in meaningful differences in clinical efficacy among different weight groups. The RA trial in MTX-experienced and TNF-blocker-naïve patients (Trial RA-2) did show evidence of a reduction in clinical efficacy with increasing body weight, but this effect was observed for both tested doses of golimumab (50 mg and 100 mg). There is no need to adjust the dosage of IMMGOLIS in adult patients based on body weight.

Specific Populations

In adults, population PK analyses suggested no PK differences between male and female patients after body-weight adjustment in the RA and UC trials. Subgroup analysis based on gender showed that both female and male patients achieved clinically significant response at the proposed clinical dose. Dosage adjustment based on gender is not needed.

Population PK analyses indicated that PK parameters of golimumab were not influenced by age in adult patients. Patients with age ≥ 65 years had apparent clearance of golimumab similar to patients with age < 65 years. No ethnicity-related PK differences were observed between Caucasians and Asians, and there were too few patients of other races to assess for PK differences.

No formal trial of the effect of renal or hepatic impairment on the PK of golimumab products was conducted.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of golimumab or of other golimumab products.

Results from the EIA Method

Using an enzyme immunoassay (EIA method), antibodies to golimumab were detected in 57 (4%) of golimumab-treated patients across the Phase 3 RA and other indications trials through Week 24. Similar rates were observed in each of the 3 indications. Patients who received golimumab with concomitant MTX had a lower proportion of antibodies to golimumab than patients who received golimumab without MTX (approximately 2% vs. 7%, respectively).

With the EIA method, the presence of serum concentrations of golimumab can interfere with the detection of antibodies to golimumab leading to inconclusive results. In adult UC trials, 34 (3%), 341 (28%) and 823 (69%) of golimumab-treated patients were positive, negative and inconclusive for antibodies to golimumab, respectively. Treatment with concomitant immunomodulators (AZA, 6-MP or MTX) resulted in a lower proportion of patients with antibodies to golimumab than patients receiving golimumab without immunomodulators (2% vs. 4%, respectively).

Of the patients with a positive antibody response to golimumab in the Phase 2 and 3 trials, most were determined to have neutralizing antibodies to golimumab as measured by a cell-based functional assay.

Results from the Drug-Tolerant EIA Method

A drug-tolerant enzyme immunoassay (drug-tolerant EIA) method for detecting antibodies to golimumab was developed and validated, which eliminated the inconclusive category as reported above. This method is approximately 16-fold more sensitive than the original EIA method with less interference from golimumab in serum.

Based on the drug tolerant EIA method, 246 (23%) of golimumab-treated patients across the Phase 3 RA, one indication, and another indication trials in adults, antibodies to golimumab were detected in 59 (16%), 106 (28%), and 81 (24%) patients, respectively. Treatment with concomitant MTX resulted in a lower proportion of patients with antibodies to golimumab than in patients receiving golimumab without MTX in RA patients (7% vs. 35%), in one indication patients (18% vs. 38%) and in another indication patients (6% vs. 29%). A trend of decreasing drug concentrations with increasing antibody titers was observed. While an overall decrease in clinical efficacy for ADA positive patients compared with ADA negative patients was not observed in patients with RA (ACR 20: 75% vs. 75%), one indication (ACR 20: 72% vs. 66%) and another indication (ASAS 20: 57% vs. 65%), higher titer antibodies may be associated with diminished efficacy.

In the UC trials in adults, 254 (21%) of golimumab-treated patients were positive for antibodies to golimumab through week 54 while the remaining 941 (79%) patients were negative. Treatment with concomitant immunomodulators (AZA, 6-MP or MTX) in the UC trials resulted in a lower proportion of patients with antibodies to golimumab than in patients receiving golimumab without immunomodulators (12% vs. 26%). There is a trend of decreasing drug concentrations with increasing antibody titers. Although the development of antibodies to golimumab did not preclude clinical response, a trend toward decreased efficacy in ADA positive patients was observed compared to ADA negative patients in the UC trials (clinical response 38% vs. 53%).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies of golimumab products have not been conducted to evaluate its carcinogenic potential. Mutagenicity studies have not been conducted with golimumab products. A fertility study conducted in mice using an analogous anti-mouse TNFα antibody administered by the intravenous route at doses up to 40 mg/kg once per week showed no impairment of fertility.

14 CLINICAL STUDIES

14.1 Rheumatoid Arthritis

The efficacy and safety of golimumab were evaluated in 3 multicenter, randomized, double-blind, controlled trials (Trials RA-1, RA-2, and RA-3) in 1542 patients ≥ 18 years of age with moderately to severely active RA, diagnosed according to the American College of Rheumatology (ACR) criteria, for at least 3 months prior to administration of trial agent. Patients were required to have at least 4 swollen and 4 tender joints. Golimumab was administered subcutaneously at doses of 50 mg or 100 mg every 4 weeks. Double-blinded controlled efficacy data were collected and analyzed through Week 24. Patients were allowed to continue stable doses of concomitant low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day) and/or NSAIDs and patients may have received oral MTX during the trials.

Trial RA-1 evaluated 445 patients who were previously treated (at least 8 to 12 weeks prior to administration of trial agent) with one or more doses of a biologic TNF blocker without a serious adverse reaction. Patients may have discontinued the biologic TNF blocker for a variety of reasons. Patients were randomized to receive placebo (N=150), golimumab 50 mg (N=147), or golimumab 100 mg (N=148). Patients were allowed to continue stable doses of concomitant MTX, sulfasalazine (SSZ), and/or hydroxychloroquine (HCQ) during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited.

Trial RA-2 evaluated 444 patients who had active RA despite a stable dose of at least 15 mg/week of MTX and who had not been previously treated with a biologic TNF blocker. Patients were randomized to receive background MTX (N=133), golimumab 50 mg + background MTX (N=89), golimumab 100 mg + background MTX (N=89), or golimumab 100 mg monotherapy (N=133). The use of other DMARDs including SSZ, HCQ, cytotoxic agents, or other biologics was prohibited.

Trial RA-3 evaluated 637 patients with active RA who were MTX naïve and had not previously been treated with a biologic TNF blocker. Patients were randomized to receive MTX (N=160), golimumab 50 mg + MTX (N=159), golimumab 100 mg + MTX (N=159), or golimumab 100 mg monotherapy (N=159). For patients receiving MTX, MTX was administered at a dose of 10 mg/week beginning at Week 0 and increased to 20 mg/week by Week 8. The use of other DMARDs including SSZ, HCQ, cytotoxic agents, or other biologics was prohibited.

The primary endpoint in Trial RA-1 and Trial RA-2 was the percentage of patients achieving an ACR 20 response at Week 14 and the primary endpoint in Trial RA-3 was the percentage of patients achieving an ACR 50 response at Week 24.

In Trials RA-1, RA-2, and RA-3, the median duration of RA disease was 9.4, 5.7, and 1.2 years and 99%, 75%, and 54% of the patients used at least one DMARD in the past, respectively. Approximately 77% and 57% of patients received concomitant NSAIDs and low dose corticosteroids, respectively, in the 3 pooled RA trials.

Clinical Response

In the 3 RA trials, a greater percentage of patients treated with the combination of golimumab and MTX achieved ACR responses at Week 14 (Trials RA-1 and RA-2) and Week 24 (Studies RA-1, RA-2, and RA-3) versus patients treated with the MTX alone. There was no clear evidence of improved ACR response with the higher golimumab dose group (100 mg) compared to the lower golimumab dose group (50 mg). In Trials RA-2 and RA-3, the golimumab monotherapy groups were not statistically different from the MTX monotherapy groups in ACR responses. Table 3 shows the proportion of patients with the ACR response for the golimumab 50-mg and control groups in Trials RA-1, RA-2, and RA-3. In the subset of patients who received golimumab in combination with MTX in Trial RA-1, the proportion of patients achieving ACR 20, 50 and 70 responses at Week 14 were 40%, 18%, and 12%, respectively, in the golimumab 50 mg + MTX group (N=101) compared with 17%, 6%, and 2%, respectively, in the placebo + MTX group (N=103). Table 4 shows the percent improvement in the components of the ACR response criteria for the golimumab 50 mg + MTX and MTX groups in Trial RA-2. The percentage of patients achieving ACR 20 responses by visit for Trial RA-2 is shown in Figure 1. ACR 20 responses were observed in 38% of patients in the golimumab 50-mg + MTX group at the first assessment (Week 4) after the initial golimumab administration.

Table 3: Trials RA-1, RA-2, and RA-3 Proportion of Patients with an ACR Response[a]

	Trial RA-1 Active RA previously treated with one or more doses of TNF blockers		**Trial RA-2 Active RA, despite MTX**		**Trial RA-3 Active RA, MTX Naïve**	
	Placebo ± DMARDs[b]	Golimumab 50 mg ± DMARDs[b]	Background MTX	Golimumab 50 mg + Background MTX	MTX	Golimumab 50 mg + MTX
N[c]	150	147	133	89	160	159
ACR 20						
Week 14	18%	35%	33%	55%	NA[e]	NA[e]
Week 24	16%	31%	28%	60%	49%	62%
ACR 50						
Week 14	7%	15%	10%	35%	NA[e]	NA[e]
Week 24	4%	16%	14%	37%	29%	40%
ACR70						
Week 14	2%	10%	4%	13%	NA[e]	NA[e]
Week 24	2%	9%	5%	20%	16%	24%[d]

[a] Approximately 78% and 58% of the patients received concomitant NSAIDs and low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day), respectively, during the 3 pooled RA trials.
[b] DMARDs in Trial RA-1 included MTX, HCQ, and/or SSZ (about 68%, 8%, and 5% of patients received MTX, HCQ, and SSZ, respectively).
[c] N reflects randomized patients.
[d] Not significantly different from MTX monotherapy.
[e] NA = Not applicable, as data was not collected at Week 14 in Trial RA-3.

Table 4: Trial RA-2 — Median Percent Improvement from Baseline in the Individual ACR Components at Week 14[a]

	Background MTX	**Golimumab 50 mg + Background MTX**
N[b]	133	89

Table 4: Trial RA-2 – Median Percent Improvement from Baseline in the Individual ACR Components at Week 14[a]

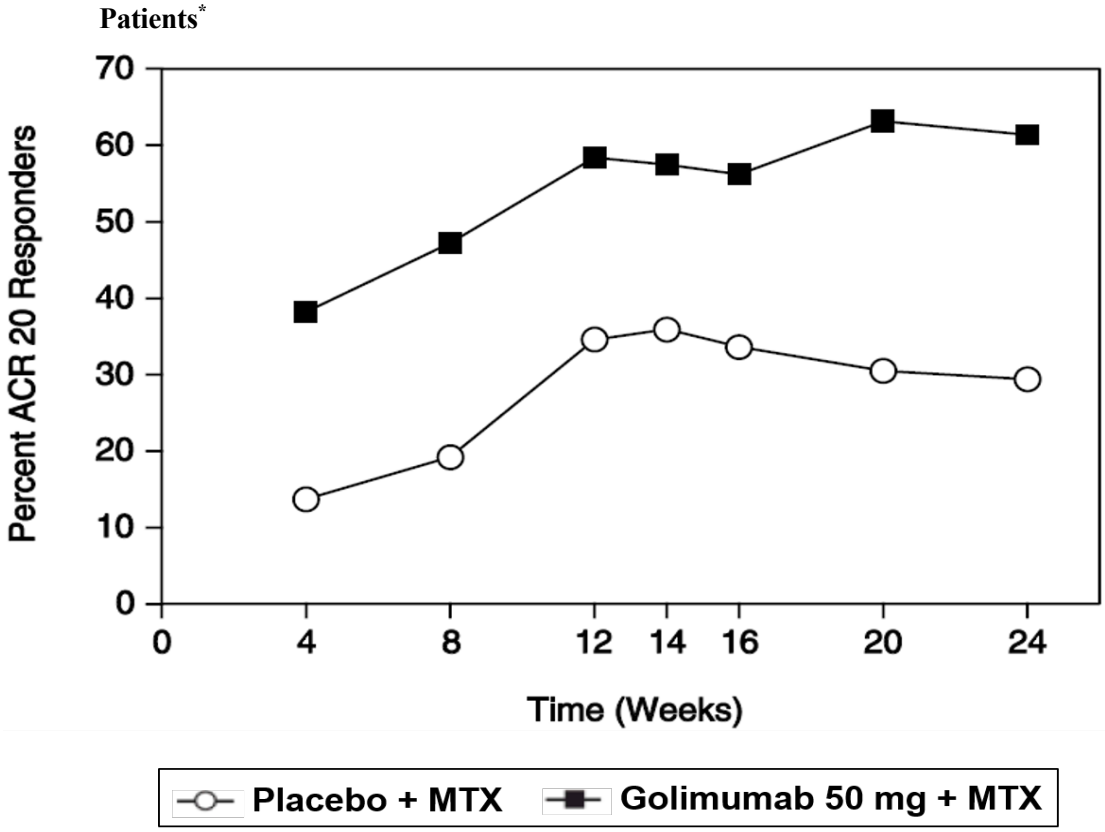
	Background MTX	Golimumab 50 mg + Background MTX
Number of swollen joints (0-66)		
Baseline	12	13
Week 14	38%	62%
Number of tender joints (0-68)		
Baseline	21	26
Week 14	30%	60%
Patient's assessment of pain (0-10)		
Baseline	5.7	6.1
Week 14	18%	55%
Patient's global assessment of disease activity (0-10)		
Baseline	5.3	6.0
Week 14	15%	45%
Physician's global assessment of disease activity (0-10)		
Baseline	5.7	6.1
Week 14	35%	55%
HAQ score (0-3)		
Baseline	1.25	1.38
Week 14	10%	29%
CRP (mg/dL)		
Baseline	0.8	1.0
Week 14	2%	44%

Note: Baseline values are medians.

[a] In Trial RA-2, about 70% and 85% of patients received concomitant low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day) and/or NSAIDs during the trials, respectively.

[b] N reflects randomized patients; actual number of patients evaluable for each endpoint may vary.

Figure 1: Trial RA-2 – Percentage of Patients Achieving ACR 20 Response by Visit: Randomized



* The same patients may not have responded at each timepoint.

Physical Function Response in Patients with RA

In Trials RA-1 and RA-2, the golimumab 50 mg groups demonstrated a greater improvement compared to the control groups in the change in mean Health Assessment Questionnaire Disability Index (HAQ-DI) score from baseline to Week 24: 0.23 vs. 0.03 in RA-1, 0.47 vs. 0.13 in RA-2, respectively. Also in Trials RA-1 and RA-2, the golimumab 50 mg groups compared to the control groups had a greater proportion of HAQ responders (change from baseline > 0.22) at Week 24: 43% vs. 27%, 65% vs. 35%, respectively.

14.2 Adult Ulcerative Colitis

The efficacy and safety of golimumab was evaluated in 2 multicenter, randomized, double-blind, placebo-controlled clinical trials in adults with moderately to severely active ulcerative colitis (UC). Trial UC-1 (NCT00487539) was a 6-week induction trial. Trial UC-2 (NCT00488631) was a randomized-withdrawal maintenance trial that evaluated 456 patients who achieved clinical response with golimumab induction and tolerated golimumab treatment.

In Trial UC-1 moderately to severely active UC was defined as a Mayo score of 6 to 12 [the Mayo score ranges from 0 to 12 and has 4 subscales that are each scored from 0 (normal) to 3 (most severe): stool frequency, rectal bleeding, findings on endoscopy, and physician global assessment]. At baseline, subjects also had an endoscopy subscore of 2 or 3 on a 3-point scale (an endoscopy score of 2 is defined by marked erythema, absent vascular pattern, friability, erosions; and a score of 3 is defined by spontaneous bleeding, ulceration). Patients were corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC) or had an inadequate response to or had failed to tolerate at least one of the following therapies: oral

aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine.

Trial UC-1 was divided into 2 parts. In Part 1 (dose finding), patients were randomized to one of 4 treatment groups: 400 mg golimumab administered subcutaneously (SC) at Week 0 and 200 mg at Week 2 (400/200 mg), 200 mg golimumab SC at Week 0 and 100 mg at Week 2 (200/100 mg), 100 mg golimumab SC at Week 0 and 50 mg at Week 2 (100/50 mg), or placebo SC at Weeks 0 and 2. In Part 2 (dose confirming), efficacy was evaluated in 761 patients who were randomized to receive either 400 mg golimumab SC at Week 0 and 200 mg at Week 2, 200 mg golimumab SC at Week 0 and 100 mg at Week 2, or placebo SC at Weeks 0 and 2. Golimumab 100/50 mg SC was not evaluated in Part 2; its safety and effectiveness has not been established in UC. Concomitant stable doses of oral aminosalicylates (5-ASA), oral corticosteroids (less than 40 mg/day), azathioprine (AZA), 6-mercaptopurine (6-MP), and/or methotrexate (MTX) were permitted. Patients who received previous TNF inhibitors were excluded. The primary endpoint in UC-1 was the percent of patients in clinical response at Week 6, defined as a decrease from baseline in the Mayo score by ≥ 30% and ≥ 3 points, accompanied by a decrease in the rectal bleeding subscore of ≥ 1 or a rectal bleeding subscore of 0 (no blood seen) or 1 (streaks of blood with stool less than half the time).

Trial UC-2 evaluated 456 patients who achieved clinical response with golimumab induction and tolerated golimumab treatment. Patients were randomized to receive golimumab 50 mg, golimumab 100 mg or placebo administered subcutaneously every 4 weeks. Concomitant stable doses of oral aminosalicylates, azathioprine, 6-mercaptopurine, and/or methotrexate were permitted. Corticosteroids were to be tapered at the start of the maintenance trial. The primary endpoint in UC-2 was the percent of patients maintaining clinical response through Week 54.

Clinical Response, Clinical Remission and Improvement of Endoscopic Appearance of the Mucosa

In Trial UC-1, a greater proportion of patients achieved clinical response, clinical remission and had improvement of endoscopic appearance of the mucosa at Week 6 in the golimumab 200/100 mg group compared with the placebo group. The golimumab 400/200 mg group did not demonstrate additional clinical benefit over the golimumab 200/100 mg group. Clinical response was defined as a decrease from baseline in the Mayo score of ≥ 30% and ≥ 3 points, accompanied by a decrease in the rectal bleeding subscore of ≥ 1 or a rectal bleeding subscore of 0 or 1. Clinical remission was defined as a Mayo score ≤ 2 points, with no individual subscore > 1. Improvement of endoscopic appearance of the mucosa was defined as a Mayo endoscopy subscore of 0 (normal or inactive disease) or 1 (erythema, decreased vascular pattern, mild friability).

In Trial UC-2, a greater proportion of patients maintained clinical response through Week 54 in the golimumab 100 mg group compared with the placebo group. In Trial UC-2, golimumab-treated patients in clinical response (which included the subset of patients in clinical remission) in Trial UC-1, were again assessed for clinical remission at Week 30 and Week 54. A greater proportion of patients had clinical remission at both Weeks 30 and 54 without demonstrating a loss of response at any time point through Week 54 in the golimumab 100 mg group compared with the placebo group.

These results are shown in Table 5 below.

Table 5: The Proportion of Patients with UC in Clinical Response, Clinical Remission and with Improvement of Endoscopic Appearance of the Mucosa in Trials UC-1 and UC-2

Trial UC-1 (6-Week Induction Trial)			
	Placebo N=251	**Golimumab 200/100 mg N=253**	**Treatment difference (95% C.I.)**
Clinical response[a] at Week 6	30%	51%	21% (12%, 29%)[*]

Table 5: The Proportion of Patients with UC in Clinical Response, Clinical Remission and with Improvement of Endoscopic Appearance of the Mucosa in Trials UC-1 and UC-2

Clinical remission[a] at Week 6	6%	18%	11% (6%, 17%)[*]
Improvement of endoscopic appearance of the mucosa at Week 6[a]	29%	42%	14% (5%, 22%)[†]
Trial UC-2 (54-Week Maintenance Trial)[b]			
	Placebo N=154	**Golimumab 100 mg N=151**	**Treatment difference (95% C.I.)**
Clinical response[a] through Week 54[c]	31%	50%	19% (8%, 29%)[‡]
Clinical remission[a] at both Week 30 and Week 54[d]	16%	28%	12% (3%, 21%)[§]

[*] p<0.0001; [†] p=0.0014; [‡] p<0.001; [§] p=0.004

[a] Patients who had a prohibited change in concomitant UC medication, an ostomy or colectomy, discontinued trial agent due to lack of therapeutic effect, or a dose adjustment in Trial UC-2 were considered not to be in clinical response, clinical remission or have an improvement in endoscopic appearance of the mucosa from the time of the event onward.

[b] Results in Trial UC-2 are based on patients who were in clinical response to golimumab at trial entry.

[c] Patients were assessed for UC disease activity by partial Mayo score every 4 weeks (loss of response was confirmed by endoscopy). Therefore, a patient who maintained clinical response was in response at each evaluation through Week 54.

[d] A patient had to be in remission at both Weeks 30 and 54 (without demonstrating a loss of response at any time point through Week 54) to achieve sustained remission.

16 HOW SUPPLIED/STORAGE AND HANDLING

IMMGOLIS (golimumab-sldi) injection is a sterile, preservative-free, clear to slightly opalescent, colorless to light yellow solution for subcutaneous use in a single-dose prefilled glass syringe. The Type 1 glass syringe has a coated stopper. The fixed stainless steel needle (5 bevel, 27G, ½ inch) is covered with a needle shield to prevent leakage of the solution through the needle and to protect the needle during handling prior to subcutaneous administration. The needle shield is made of a dry natural rubber.

50 mg/0.5 mL single-dose prefilled syringe	1 pack	NDC 69448-028-63
100 mg/mL single-dose prefilled syringe	1 pack	NDC 69448-029-63

Storage and Handling

Refrigerate IMMGOLIS at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light until the time of use. Do not freeze. Do not shake. Do not use IMMGOLIS beyond the expiration date (EXP) on the carton or the expiration date on the prefilled syringe.

If needed, IMMGOLIS may be stored at room temperature up to 77°F (25°C) for a maximum single period of 15 days in the original carton to protect from light. Once a syringe has been stored at room temperature, do not return the product to the refrigerator. If not used within 15 days at room temperature, discard IMMGOLIS.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide and Instructions for Use)

Patients should be advised of the potential benefits and risks of IMMGOLIS. Physicians should instruct their patients to read the Medication Guide before starting IMMGOLIS therapy and to read it each time the prescription is renewed.

Infections

Inform patients that IMMGOLIS may lower the ability of their immune system to fight infections. Advise patients not to start taking IMMGOLIS if they have an active infection. Instruct patients to contact their healthcare provider if they develop any symptoms of infection, including tuberculosis, invasive fungal infections, and hepatitis B reactivation *[see Warnings and Precautions (5.1, 5.5)]*.

Malignancies

Inform patients that IMMGOLIS may increase their risk of lymphoma and other malignancies while receiving IMMGOLIS *[see Warnings and Precautions (5.2)]*.

Hypersensitivity Reactions

Advise patients to stop taking IMMGOLIS and contact their healthcare provider immediately if they experience any symptoms of hypersensitivity reactions while taking IMMGOLIS *[see Warnings and Precautions (5.12)]*.

Advise latex-sensitive patients that the needle cover on the prefilled syringe contains dry natural rubber (a derivative of latex) *[see How Supplied/Storage and Handling (16)]*.

Other Medical Conditions

Advise patients to report any signs of new or worsening medical conditions such as congestive heart failure, demyelinating disorders, autoimmune diseases, liver disease, or cytopenias *[see Warnings and Precautions (5.3, 5.4, 5.5, 5.6, 5.10)]*.

Instructions for Safe Administration

The first injection should be performed under the supervision of a qualified healthcare professional.

If a patient or caregiver is to administer IMMGOLIS, he/she should be instructed in injection techniques and their ability to inject subcutaneously should be assessed to ensure the proper administration of IMMGOLIS.

Advise the patient to read the FDA-approved Instructions for Use and provide the following instructions to patients:

- Prior to use, remove the prefilled syringe from the refrigerator and allow IMMGOLIS to sit at room temperature outside of the carton for at least 30 minutes and out of the reach of children.
- Do not warm IMMGOLIS in any other way. For example, do not warm IMMGOLIS in a microwave or in hot water.
- Do not remove the prefilled syringe needle cover while allowing IMMGOLIS to reach room temperature. Remove these immediately before injection.
- A puncture-resistant container for disposal of needles and syringes should be used. Patients or caregivers should be instructed in the technique of proper syringe and needle disposal, and be advised not to reuse these items.

Manufactured by:
Accord BioPharma, Inc.
8041 Arco Corporate Drive,
Suite 200, Raleigh, NC 27617 USA

US License No. 2105

MEDICATION GUIDE

IMMGOLIS™ (im-goe-lis)

(golimumab-sldi)

injection, for subcutaneous use

What is the most important information I should know about IMMGOLIS?

IMMGOLIS is a medicine that affects your immune system. IMMGOLIS can lower the ability of your immune system to fight infections. Some people have serious infections while taking golimumab products, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that spread throughout their body. Some people have died from these serious infections.

- Your doctor should test you for TB and hepatitis B before starting IMMGOLIS.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with IMMGOLIS.

You should not start taking IMMGOLIS if you have any kind of infection unless your doctor says it is okay.

Before starting IMMGOLIS, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
    - fever, sweat, or chills
    - muscle aches
    - cough
    - shortness of breath
    - blood in phlegm
    - weight loss
    - warm, red, or painful skin or sores on your body
    - diarrhea or stomach pain
    - burning when you urinate or urinate more often than normal
    - feel very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live, have lived, or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may happen or become more severe if you use IMMGOLIS. Ask your doctor if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B.
- use the medicine ORENCIA (abatacept), KINERET (anakinra), ACTEMRA (tocilizumab) or RITUXAN (rituximab).

After starting IMMGOLIS, call your doctor right away if you have any symptoms of an infection. IMMGOLIS can make you more likely to get infections or make worse any infection that you have.

Cancer

- For children and adults taking TNF-blocker medicines, including IMMGOLIS, the chances of getting cancer may increase.
- There have been cases of unusual cancers in children and teenage patients taking TNF-blocking agents.
- People with inflammatory diseases including rheumatoid arthritis especially those with very active disease, may be more likely to get lymphoma.
- Some people receiving medicines that are like IMMGOLIS, called TNF blockers, developed a rare type of cancer called hepatosplenic T cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men. Also, most people were being treated for Crohn's disease or ulcerative colitis with a TNF blocker and another medicine called azathioprine or 6 mercaptopurine (6-MP).
- Some people treated with golimumab products have developed certain kinds of skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with IMMGOLIS, tell your doctor.
- You should see your doctor periodically for skin examinations, especially if you have a history of skin cancer.

What is IMMGOLIS?

IMMGOLIS is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker. IMMGOLIS is used to treat:

- adults with the medicine methotrexate to treat moderately to severely active rheumatoid arthritis (RA).
- adults with moderately to severely active ulcerative colitis (UC)

You may continue to use other medicines that help treat your condition while taking IMMGOLIS, such as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

IMMGOLIS is not indicated for the treatment of children.

What should I tell my doctor before starting treatment with IMMGOLIS?

IMMGOLIS may not be right for you. See "**What is the most important information I should know about IMMGOLIS?**".

Before starting IMMGOLIS, tell your doctor about all your medical conditions, including if you:

- have an infection.
- have or have had lymphoma or any other type of cancer.
- have or had heart failure.
- have or have had a condition that affects your nervous system, such as multiple sclerosis or Guillain-Barré syndrome.
- have recently received or are scheduled to receive a vaccine. People taking IMMGOLIS should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer). People taking IMMGOLIS can receive non-live vaccines.
- have a baby and you were using IMMGOLIS during your pregnancy. Tell your baby's doctor before your baby receives any vaccine. Your baby may have an increased chance of getting an infection for up to 6 months after birth.
- are allergic to rubber or latex. The needle cover on the prefilled syringe contains dry natural rubber.
- are pregnant or planning to become pregnant. It is not known if IMMGOLIS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. You and your doctor should decide if you will take IMMGOLIS or breastfeed.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially, tell your doctor if you:

- use ORENCIA (abatacept) or KINERET (anakinra). You should not take IMMGOLIS while you are also taking ORENCIA (abatacept) or KINERET (anakinra).
- use other TNF-blocker medicines, including REMICADE (infliximab), HUMIRA (adalimumab), ENBREL (etanercept), or CIMZIA (certolizumab pegol).
- receive RITUXAN (rituximab) or ACTEMRA (tocilizumab).

Ask your doctor if you are not sure if your medicine is one listed above.

Keep a list of all your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I use IMMGOLIS?

- IMMGOLIS is given as an injection under the skin (subcutaneous injection).
- IMMGOLIS comes in a prefilled syringe.
- If your doctor decides that you or a caregiver may be able to give your injections of IMMGOLIS at home, **you should receive training on the right way to prepare and inject IMMGOLIS. Do not try to inject IMMGOLIS yourself until you have been shown the right way to give the injections by your doctor or nurse.**
- Use IMMGOLIS exactly as prescribed by your doctor. Your doctor will tell you how much IMMGOLIS to inject and when to inject it depending on your medical condition.
- See the detailed **Instructions for Use** that comes with your IMMGOLIS for information about the right way to prepare and give your IMMGOLIS injections at home.
- Do not miss any doses of IMMGOLIS. If you miss a dose of IMMGOLIS, inject the missed dose as soon as possible. Then, take your next dose at your regular scheduled time. In case you are not sure when to inject IMMGOLIS, call your doctor or pharmacist.

What are the possible side effects of IMMGOLIS?

IMMGOLIS can cause serious side effects, including:

See "**What is the most important information I should know about IMMGOLIS?**"

Serious Infections.

- Some patients have an increased chance of getting serious infections while receiving IMMGOLIS. These serious infections include TB and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients die from these infections. **Do not** start using IMMGOLIS if you have an active infection. If you get an infection while receiving treatment with IMMGOLIS your doctor will treat your infection and may need to stop your IMMGOLIS treatment. Tell your doctor right away if you have any of the following signs of an infection while taking or after taking IMMGOLIS:
    - a fever
    - feel very tired
    - have a cough
    - have flu-like symptoms
    - warm, red, or painful skin
- Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with IMMGOLIS and during treatment with IMMGOLIS. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you are taking IMMGOLIS. People who had a negative TB skin test before receiving golimumab products have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking IMMGOLIS:
    - cough that does not go away
    - low grade fever
    - weight loss
    - loss of body fat and muscle (wasting)

Hepatitis B infection in people who carry the virus in their blood.

- If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use IMMGOLIS. Your doctor should do blood tests before you start treatment with IMMGOLIS and while you are using IMMGOLIS. Tell your doctor if you have any of the following symptoms of a possible hepatitis B infection:
    - feel very tired
    - dark urine
    - skin or eyes look yellow
    - little or no appetite
    - vomiting
    - muscle aches
    - clay-colored bowel movements
    - fevers
    - chills
    - stomach discomfort
    - skin rash

Heart failure, including new heart failure or worsening of heart failure that you already have can happen in people who use TNF-blocker medicines, including IMMGOLIS. If you develop new or worsening heart failure with IMMGOLIS, you may need to be treated in a hospital, and it may result in death.

- If you have heart failure before starting IMMGOLIS, your condition should be watched closely during treatment with IMMGOLIS.
- Call your doctor right away if you get new or worsening symptoms of heart failure during treatment with IMMGOLIS (such as shortness of breath or swelling of your lower legs or feet, or sudden weight gain).

Nervous System Problems. Rarely, people using TNF-blocker medicines, including IMMGOLIS, have nervous system problems such as multiple sclerosis or Guillain-Barré syndrome. Tell your doctor right away if you get any of these symptoms:

- vision changes
- weakness in your arms or legs
- numbness or tingling in any part of your body

Immune System Problems. Rarely, people using TNF-blocker medicines have developed symptoms that are like the symptoms of lupus. Tell your doctor if you have any of these symptoms:

- a rash on your cheeks or other parts of the body
- sensitivity to the sun
- new joint or muscle pains
- becoming very tired
- chest pain or shortness of breath
- swelling of the feet, ankles, or legs

Liver Problems. Liver problems can happen in people who use TNF-blocker medicines, including IMMGOLIS. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms:

- feel very tired
- skin or eyes look yellow
- poor appetite or vomiting
- pain on the right side of your stomach (abdomen)

Blood Problems. Low blood counts have been seen with golimumab products. Your body may not make enough blood cells

that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding easily, or looking pale. Your doctor will check your blood counts before and during treatment with IMMGOLIS.

Allergic Reactions. Allergic reactions can happen in people who receive TNF-blocker medicines, including IMMGOLIS. Some reactions may be serious and can be life-threatening. Some of these reactions can happen after receiving your first dose of IMMGOLIS. Stop using IMMGOLIS and call your doctor right away if you have any of these symptoms of an allergic reaction:

- hives
- swollen face
- breathing trouble
- chest pain

The most common side effects of IMMGOLIS include:

- upper respiratory infection (runny nose, sore throat, and hoarseness or laryngitis)
- reaction at the site of injection (redness, swelling, itching, pain, bruising, or tingling)
- viral infections such as flu and oral cold sores

Psoriasis. Some people using golimumab products had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus. Your doctor may decide to stop your treatment with IMMGOLIS.

These are not all of the possible side effects of IMMGOLIS. Tell your doctor about any side effect that bothers you or does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store IMMGOLIS?

- Refrigerate IMMGOLIS between 36ºF to 46ºF (2ºC to 8ºC).
- If needed, you may store IMMGOLIS at room temperature up to 77ºF (25ºC) for one period of time up to 15 days.
  - Write the date of that you remove IMMGOLIS from the refrigerator on the carton.
  - If IMMGOLIS has reached room temperature, do not put it back in the refrigerator.
  - Throw away IMMGOLIS if it has been kept at room temperature for 15 days and has not been used.
- **Do not** freeze IMMGOLIS.
- Keep IMMGOLIS in the original carton to protect it from light when not being used.
- **Do not** shake IMMGOLIS.
- Do not use IMMGOLIS after the expiration date on the carton or on the prefilled syringe.

Keep IMMGOLIS and all medicines out of the reach of children.

General information about the safe and effective use of IMMGOLIS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use IMMGOLIS for a condition for which it was not prescribed. Do not give IMMGOLIS to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about IMMGOLIS. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about IMMGOLIS that is written for health professionals. For more information go to www.immgolis.com or call 1-866-941-7875.

What are the ingredients in IMMGOLIS?

Active ingredient: golimumab-sldi.

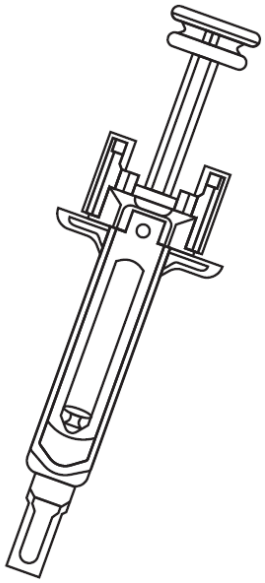
Inactive ingredients: histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, trehalose, and water for injection. IMMGOLIS does not contain preservatives.

Manufactured by: Accord BioPharma, Inc. 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617 USA

US License No. 2105

This Medication Guide has been approved by the U.S. Food and Drug Administration Issued: 05/2026

Instructions for Use
IMMGOLIS™ (im-goe-lis)
(golimumab-sldi)
injection, for subcutaneous use
Prefilled Syringe



SINGLE DOSE

Important

IMMGOLIS comes as a single-dose prefilled syringe containing one 50 mg or one 100 mg dose. Each IMMGOLIS prefilled syringe can only be used one time. Throw away (dispose of) the used prefilled syringe (See Step 3) after one dose, even if there is medicine left in it. Do not reuse your IMMGOLIS prefilled syringe.

If your healthcare provider decides that you or a caregiver may be able to give your injections of IMMGOLIS at home, you should receive training on the right way to prepare and inject IMMGOLIS using the prefilled syringe before attempting to inject.

Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.

Read this Instructions for Use before using your IMMGOLIS prefilled syringe and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

The IMMGOLIS prefilled syringe is intended for injection under the skin, not into the muscle or vein. After injection, the needle will retract into the body of the device and lock into place.

Storage information

Store IMMGOLIS in the refrigerator at **36° to 46°F** (2° to 8°C). If needed, store IMMGOLIS at room temperature, up to 77°F (25°C) for one period of time up to 15 days. Do not return it to the refrigerator.

Throw away (dispose of) if not used within 15 days at room temperature.

Do not freeze IMMGOLIS prefilled syringe.

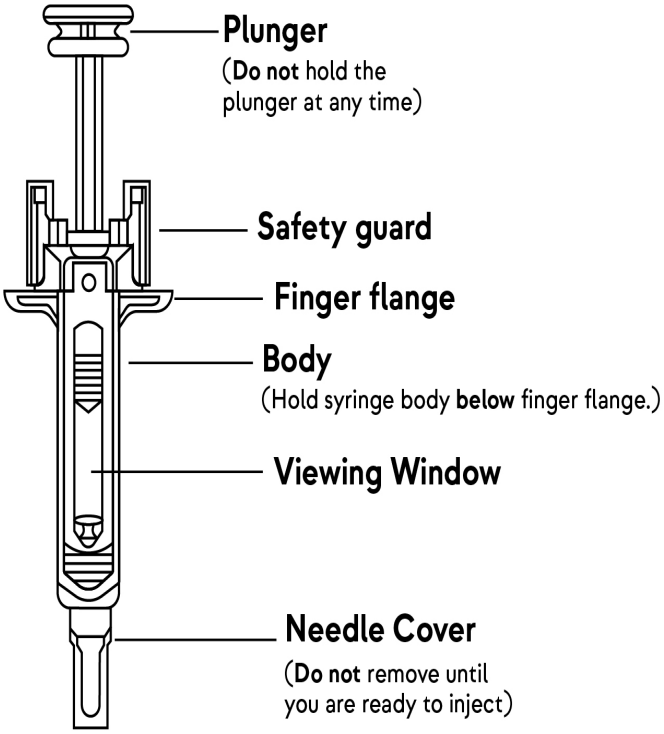
Do not shake IMMGOLIS prefilled syringe.

Keep IMMGOLIS prefilled syringe in the original carton to protect from light before use.

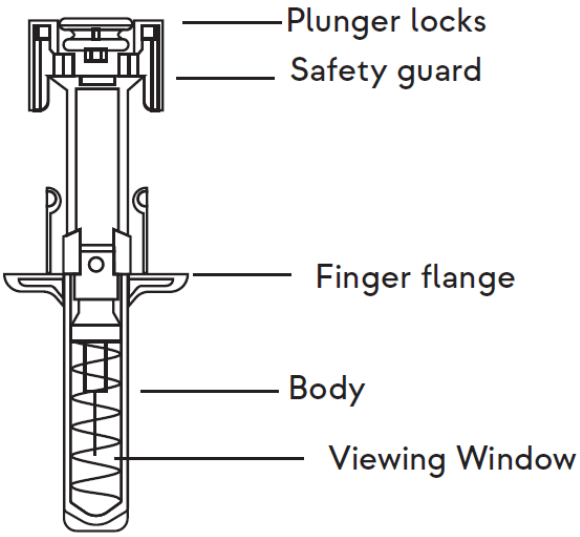
Keep IMMGOLIS prefilled syringe and all medicines out of the reach of children.

Prefilled syringe parts

Before use



After use



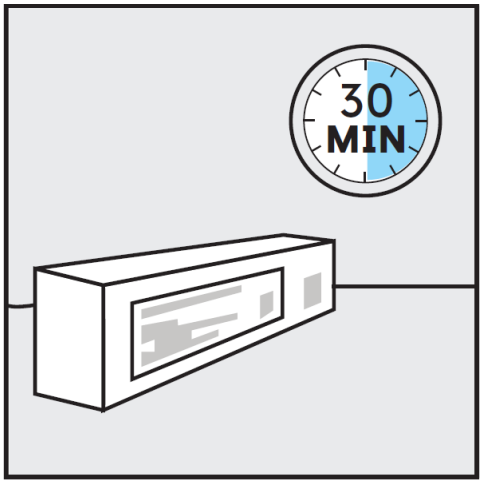
You will need these supplies:

- **1 IMMGOLIS prefilled syringe**

Not provided in the IMMGOLIS prefilled syringe carton:

- **1 Alcohol swab**
- **1 Cotton ball or gauze pad**
- **1 Adhesive bandage**
- **1 Sharps container** (See Step 3)

1. Prepare for your injection



Inspect carton

Remove your IMMGOLIS prefilled syringe carton from the refrigerator.

Remove the prefilled syringe from the carton and let it sit on a flat surface at room temperature for **at least 30 minutes** before use.

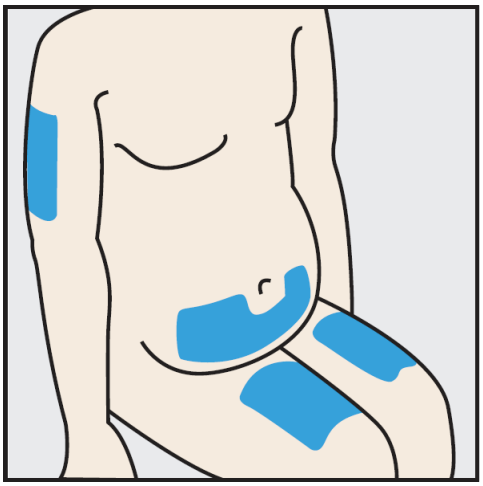
Do not warm the prefilled syringe any other way.

Check the expiration date ('EXP') on the back panel of the carton and on the prefilled syringe

(through the viewing window).

Do not use your prefilled syringe if the expiration date has passed.

Do not inject IMMGOLIS if the perforations on the carton are broken. Call your healthcare provider or pharmacist for a refill.



Choose injection site

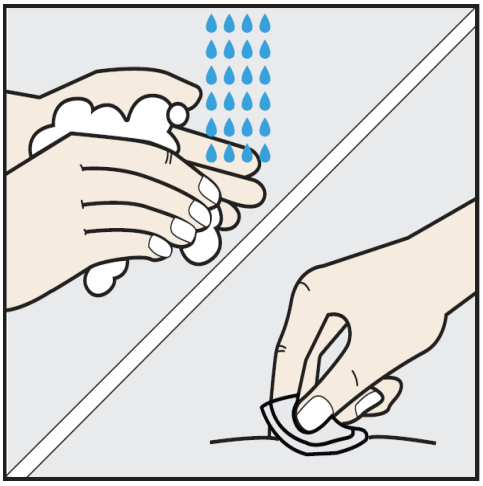
Select from the following areas for your injection:

- **Front of thighs** (recommended)
- Lower stomach area (lower abdomen), except for a 2-inch area right around your navel (belly-button)
- Back of upper arms (only if someone else is giving you the injection)

Choose a different site within your preferred area for each injection.

Do not inject into skin that is tender, bruised, red, hard, thick or scaly.

Do not inject into areas with scars or stretch marks.

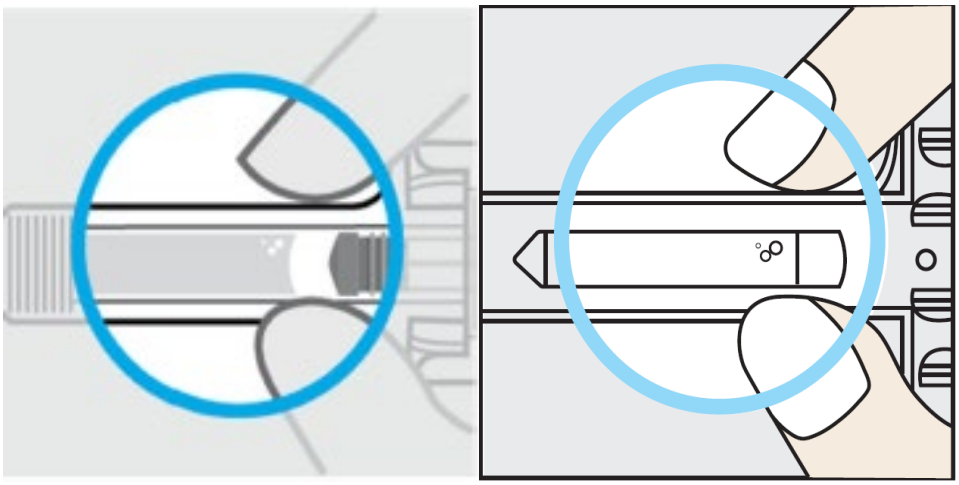


Clean injection site

Wash your hands well with soap and warm water.

Wipe your chosen injection site with an alcohol swab and allow it to dry.

Do not touch, fan, or blow on the injection site after you have cleaned it.

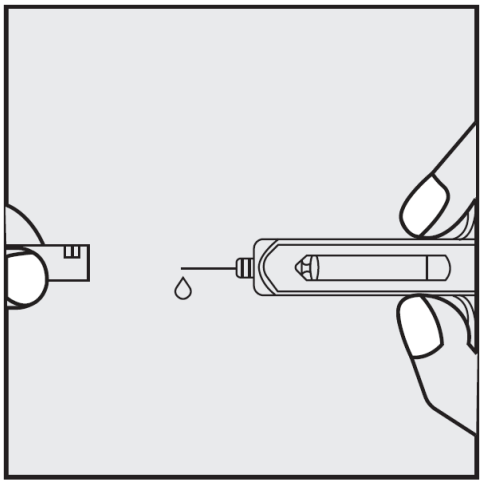


Inspect liquid

Check the IMMGOLIS prefilled syringe liquid in the viewing window. It should be clear to slightly opalescent, colorless to light yellow. You may also see one or more air bubbles. This is normal.

Do not inject if the liquid is cloudy or discolored, or has foreign particles. Call your healthcare provider or pharmacist for a refill.

2. Inject IMMGOLIS using prefilled syringe



Remove needle cover

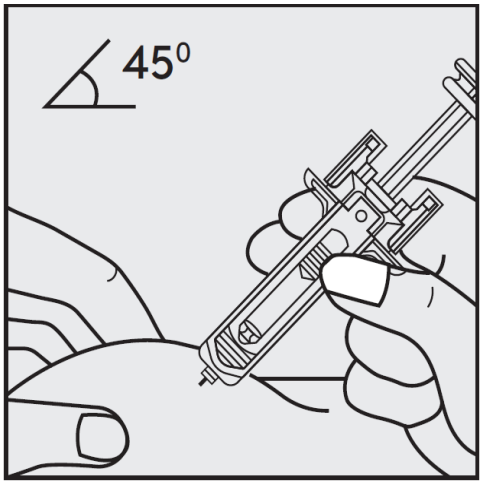
Hold your prefilled syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

Inject IMMGOLIS within 5 minutes of removing the needle cover.

Do not put needle cover back on, as this may damage the needle or cause a needle stick injury.

Do not touch needle or let it touch any surface.

Do not use a IMMGOLIS prefilled syringe if it is dropped. Call your healthcare provider or pharmacist for a refill.



Position fingers and insert needle

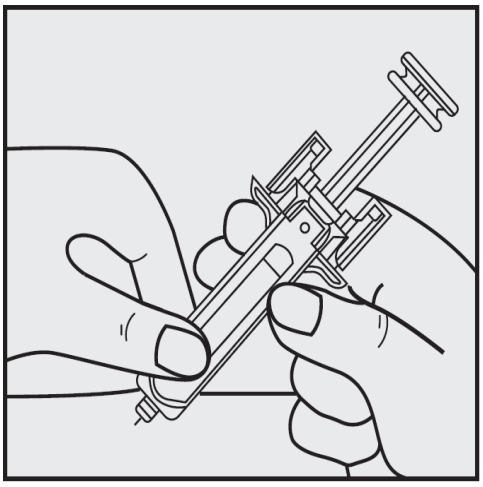
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.

Use your other hand to pinch skin at the injection site. Position syringe at about a 45 degree angle to the skin.

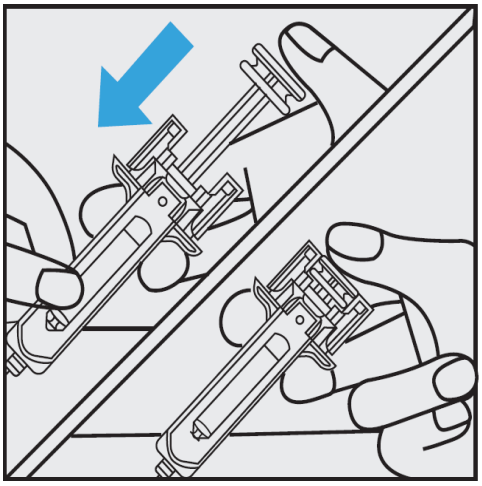
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



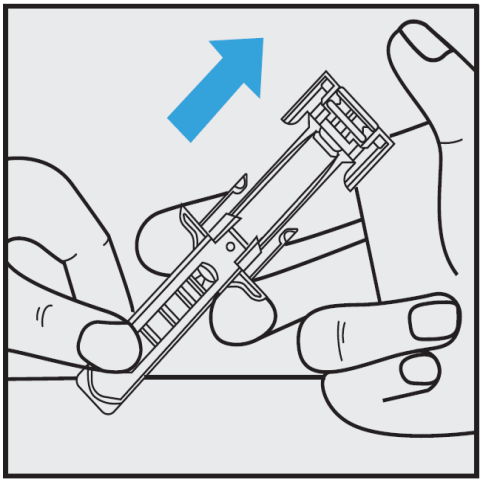
Release pinch and reposition hand

Use your free hand to grasp the body of the prefilled syringe.



Press plunger

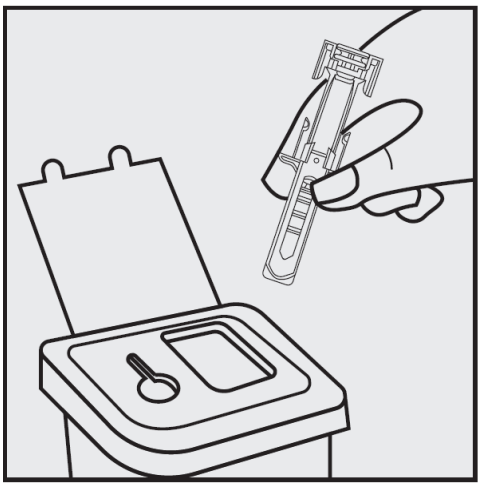
Place thumb from the opposite hand on the plunger and press the plunger **all the way down until it stops.**



Release pressure from plunger

The safety guard will cover the needle and lock into place, removing the needle from your skin.

3. After your injection



Dispose of your prefilled syringe

Put your used IMMGOLIS prefilled syringe in an approved sharps disposal container right away after use.

Do not throw away (dispose of) your used IMMGOLIS prefilled syringe in your household trash.

Do not recycle your used sharps disposal container.

For more information, see "How should I dispose of the used prefilled syringe?"

Check injection site

There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site.

If needed, cover injection site with a bandage.

Need help?

Call your healthcare provider to talk about any questions you may have. For additional assistance

or to share your feedback call 1-866-941-7875.

How should I dispose of the used prefilled syringe?

If you do not have an approved sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away (dispose of) used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: www.fda.gov/safesharpsdisposal

Manufactured by:

Accord BioPharma, Inc.

8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617 USA

US License No. 2105

This Instructions for Use has been approved by the U.S. Food and Drug Administration

Approved: 05/2026

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use IMMGOLIS INTRI safely and effectively. See full prescribing information for IMMGOLIS INTRI.

IMMGOLIS INTRI™ (golimumab-sldi) injection, for intravenous use
Initial U.S. Approval: 2026

IMMGOLIS INTRI (golimumab-sldi) is a biosimilar* to SIMPONI ARIA (golimumab).

WARNING: SERIOUS INFECTIONS and MALIGNANCY
See full prescribing information for complete boxed warning.

- **Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal (such as histoplasmosis), and other opportunistic infections have occurred in patients receiving golimumab products (5.1).**
- **Discontinue IMMGOLIS INTRI if a patient develops a serious infection or sepsis (5.1).**
- **Perform test for latent TB; if positive, start treatment for TB prior to starting IMMGOLIS INTRI (5.1).**
- **Monitor all patients for active TB during treatment, even if initial latent TB test is negative (5.1).**
- **Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which IMMGOLIS INTRI is a member (5.2).**

----------INDICATIONS AND USAGE ----------

IMMGOLIS INTRI is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate (1.1)

----------DOSAGE AND ADMINISTRATION----------

- Adult patients with Rheumatoid Arthritis:
  - 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter (2.1)
- Dilution of supplied IMMGOLIS INTRI solution with 0.9% Sodium Chloride Injection, USP is required prior to administration.

----------DOSAGE FORMS AND STRENGTHS----------

- Injection: 50 mg/4 mL (12.5 mg/mL) solution in a single-dose vial (3)

----------CONTRAINDICATIONS----------

- None (4)

----------WARNINGS AND PRECAUTIONS----------

- Serious Infections: Do not start IMMGOLIS INTRI during an active infection. If an infection develops, monitor carefully, and stop IMMGOLIS INTRI if infection becomes serious (5.1).
- Invasive Fungal Infections: For patients who develop a systemic illness on IMMGOLIS INTRI, consider empiric antifungal therapy for those who reside in or travel to regions where mycoses are endemic (5.1).
- Hepatitis B Reactivation: Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop IMMGOLIS INTRI and begin anti-viral therapy (5.1).
- Malignancies: More cases of lymphoma have been observed among patients receiving TNF blockers compared with patients in the control groups. Cases of other malignancies have been observed among patients receiving TNF blockers (5.2).
- Congestive Heart Failure: Worsening, or new onset, may occur. Stop IMMGOLIS INTRI if new or worsening symptoms occur (5.3).
- Demyelinating Disorders: Exacerbation or new onset may occur (5.4).
- Lupus-like Syndrome: Discontinue IMMGOLIS INTRI if symptoms develop (5.5).
- Hypersensitivity Reactions: Serious systemic hypersensitivity reactions including anaphylaxis may occur (5.11).

----------ADVERSE REACTIONS----------

Most common adverse reactions (incidence ≥ 3%) are: upper respiratory tract infection, alanine aminotransferase increased, viral infection, aspartate aminotransferase increased, neutrophil count decreased, bronchitis, hypertension, and rash (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Accord BioPharma, Inc. at 1-866-941-7875 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------

- Biologics, including abatacept and anakinra: Increased risk of serious infections (5.1, 5.6, 5.7, 5.8, 7.2).
- Live vaccines should not be given with IMMGOLIS INTRI (5.10, 7.3).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of IMMGOLIS INTRI has been demonstrated for the condition(s) of use (e.g. indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Revised: 05/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

17 PATIENT COUNSELLING INFORMATION not listed.

*Sections or subsections omitted from the full prescribing information are

Reference ID: 5799301

FULL PRESCRIBING INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

SERIOUS INFECTIONS

Patients treated with golimumab products are at increased risk for developing serious infections that may lead to hospitalization or death *[see Warnings and Precautions (5.1)]*. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue IMMGOLIS INTRI if a patient develops a serious infection.

Reported infections with TNF blockers, of which IMMGOLIS INTRI is a member, include:

- **Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before IMMGOLIS INTRI use and during therapy. Initiate treatment for latent tuberculosis prior to IMMGOLIS INTRI use.**

- **Invasive fungal infections including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric antifungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**

- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Consider the risks and benefits of treatment with IMMGOLIS INTRI prior to initiating therapy in patients with chronic or recurrent infection.

Monitor patients closely for the development of signs and symptoms of infection during and after treatment with IMMGOLIS INTRI, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy *[see Warnings and Precautions (5.1)]*.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF-blockers, of which IMMGOLIS INTRI is a member *[see Warnings and Precautions (5.2)]*.

1 INDICATIONS AND USAGE

1.1 Rheumatoid Arthritis (RA)

IMMGOLIS INTRI, in combination with methotrexate (MTX), is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage in Adults with Rheumatoid Arthritis

The IMMGOLIS INTRI dosage regimen is 2 mg per kg given as an intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter. Follow the dilution and administration instructions for IMMGOLIS INTRI *[see Dosage and Administration (2.4)]*.

For patients with rheumatoid arthritis (RA), IMMGOLIS INTRI should be given in combination with methotrexate.

The efficacy and safety of switching between intravenous and subcutaneous formulations and routes of administration have not been established.

2.2 Evaluation for Tuberculosis and Hepatitis B Prior to Dosage

Prior to initiating IMMGOLIS INTRI and periodically during therapy, evaluate patients for active tuberculosis and test for latent infection *[see Warnings and Precautions (5.1)]*. Prior to initiating IMMGOLIS INTRI, test patients for hepatitis B viral infection *[see Warnings and Precautions (5.1)]*.

2.3 Important Administration Instructions

IMMGOLIS INTRI solution for intravenous infusion should be diluted by a healthcare professional using aseptic technique as follows:

1. Calculate the dosage and the number of IMMGOLIS INTRI vials needed based on the recommended adult dosage of 2 mg/kg and the patient's weight for RA Each 4 mL vial of IMMGOLIS INTRI contains 50 mg of golimumab-sldi.
2. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Check that the solution in each vial is clear, colorless to light yellow. Do not use if opaque particles, discoloration, or other foreign particles are present.
3. Dilute the total volume of the IMMGOLIS INTRI solution with 0.9% Sodium Chloride Injection to a final volume of 100 mL. For example, this can be accomplished by withdrawing a volume of the 0.9% Sodium Chloride Injection from the 100-mL infusion bag or bottle equal to the total volume of IMMGOLIS INTRI. Slowly add the total volume of IMMGOLIS INTRI solution to the 100-mL infusion bag or bottle. Gently mix. Discard any unused solution remaining in the vials.
4. Prior to infusion, visually inspect the diluted IMMGOLIS INTRI solution for particulate matter or discoloration. Do not use if these are present.
5. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.22 micrometer or less).
6. Do not infuse IMMGOLIS INTRI concomitantly in the same intravenous line with other agents. No physical biochemical compatibility studies have been conducted to evaluate the use of IMMGOLIS INTRI with other intravenous agents in the same intravenous line.
7. Infuse the diluted solution over 30 minutes.
8. Once diluted, the infusion solution can be stored for up to 4 hours at room temperature.

3 DOSAGE FORMS AND STRENGTHS

Injection: 50 mg/4 mL (12.5 mg/mL) clear, colorless to light yellow solution in a single-dose vial.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Infections

Patients treated with golimumab products are at increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death.

Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, or parasitic organisms including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis, and tuberculosis have been reported with TNF-blockers. Patients have frequently presented with disseminated rather than localized disease. The concomitant use of a TNF-blocker and abatacept or anakinra was associated with a higher risk of serious infections; therefore, the concomitant use of IMMGOLIS INTRI and these biologic products is not recommended *[see Warnings and Precautions (5.6, 5.7) and Drug Interactions (7.2)]*.

Treatment with IMMGOLIS INTRI should not be initiated in patients with an active infection, including clinically important localized infections. Patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants such as corticosteroids or methotrexate may be at greater risk of infection. Consider the risks and benefits of treatment prior to initiating IMMGOLIS INTRI in patients:

- with chronic or recurrent infection;
- who have been exposed to tuberculosis;
- with a history of an opportunistic infection;
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis; or
- with underlying conditions that may predispose them to infection.

Monitoring

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with IMMGOLIS INTRI. Discontinue IMMGOLIS INTRI if a patient develops a serious infection, an opportunistic infection, or sepsis. For patients who develop a new infection during treatment with IMMGOLIS INTRI, perform a prompt and complete diagnostic workup appropriate for an immunocompromised patient and initiate appropriate antimicrobial therapy and closely monitor them.

Tuberculosis

Cases of reactivation of tuberculosis or new tuberculosis infections have been observed in patients receiving TNF-blockers, including patients who have previously received treatment for latent or active tuberculosis. Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating IMMGOLIS INTRI and periodically during therapy.

Treatment of latent tuberculosis infection prior to therapy with TNF-blockers has been shown to reduce the risk of tuberculosis reactivation during therapy. Prior to initiating IMMGOLIS INTRI, 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-Guerin (BCG).

Consider anti-tuberculosis therapy prior to initiation of IMMGOLIS INTRI in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consultation with a physician with expertise in the treatment of tuberculosis is recommended to aid in the decision whether initiating anti-tuberculosis therapy is appropriate for an individual patient.

Cases of active tuberculosis have occurred in patients treated with the subcutaneous formulation of golimumab products during and after treatment for latent tuberculosis. Monitor patients for the development of signs and symptoms of tuberculosis including patients who tested negative for latent tuberculosis infection prior to initiating therapy, patients who are on treatment for latent tuberculosis, or patients who were previously treated for tuberculosis infection.

Consider tuberculosis in the differential diagnosis in patients who develop a new infection during IMMGOLIS INTRI treatment, especially in patients who have previously or recently traveled to countries with a high prevalence of tuberculosis, or who have had close contact with a person with active tuberculosis.

Invasive Fungal Infections

If patients develop a serious systemic illness and they reside or travel in regions where mycoses are endemic, consider invasive fungal infection in the differential diagnosis. Consider appropriate empiric antifungal therapy and take into account both the risk for severe fungal infection and the risks of antifungal therapy while a diagnostic workup is being performed. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. To aid in the management of such patients, consider consultation with a physician with expertise in the diagnosis and treatment of invasive fungal infections.

Hepatitis B Virus Reactivation

The use of TNF-blockers, of which IMMGOLIS INTRI is a member, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic hepatitis B carriers (i.e., surface antigen positive). In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal. The majority of these reports have occurred in patients who received concomitant immunosuppressants.

All patients should be tested for HBV infection before initiating TNF-blocker therapy. For patients who test positive for hepatitis B surface antigen, consultation with a physician with expertise in the treatment of hepatitis B is recommended before initiating TNF-blocker therapy. The risks and benefits of treatment should be considered prior to prescribing TNF-blockers, including IMMGOLIS INTRI, to patients who are carriers of HBV. Adequate data are not available on whether antiviral therapy can reduce the risk of HBV reactivation in HBV carriers who are treated with TNF-blockers. Patients who are carriers of HBV and require treatment with TNF-blockers should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy.

In patients who develop HBV reactivation, TNF-blockers should be stopped and antiviral therapy with appropriate supportive treatment should be initiated. The safety of resuming TNF-blockers after HBV reactivation has been controlled is not known. Therefore, prescribers should exercise caution when considering resumption of TNF-blockers in this situation and monitor patients closely.

5.2 Malignancies

Malignancies in Pediatric Patients

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤ 18 years of age), including golimumab products. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression, and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months (range 1 to 84 months) after the first dose of TNF-blocker therapy. Most of the patients were receiving concomitant immunosuppressants. Most cases were reported postmarketing and are derived from a variety of sources, including registries and spontaneous postmarketing reports.

Malignancies in Adult Patients

The risks and benefits of TNF-blocker treatment including IMMGOLIS INTRI should be considered prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing a TNF-blocker in patients who develop a malignancy.

In the controlled portions of clinical trials of TNF-blockers including the subcutaneous formulation of golimumab more cases of lymphoma have been observed among patients receiving anti-TNF treatment compared with patients in the control groups. Patients with RA and other chronic inflammatory diseases, particularly patients with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk (up to several fold) than the general population for the development of lymphoma, even in the absence of TNF-blocking therapy. Cases of acute and chronic leukemia have been reported with TNF-blocker use, including golimumab products, in rheumatoid arthritis and other indications. Even in the absence of TNF-blocker therapy, patients with rheumatoid arthritis may be at a higher risk (approximately 2-fold) than the general population for the development of leukemia.

Rare postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF-blocking agents. This rare type of T-cell lymphoma has a very aggressive disease course and is usually fatal. Nearly all of the reported TNF-blocker associated cases have occurred in patients with Crohn's disease or ulcerative colitis. The majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine (AZA) or 6-mercaptopurine (6–MP) concomitantly with a TNF-blocker at or prior to diagnosis. A risk for the development for hepatosplenic T-cell lymphoma in patients treated with TNF-blockers cannot be excluded.

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocking agents, including golimumab products. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

In controlled trials of other TNF-blockers in patients at higher risk for malignancies (e.g., patients with chronic obstructive pulmonary disease [COPD], patients with Wegener's granulomatosis treated with concomitant cyclophosphamide) a greater portion of malignancies occurred in the TNF-blocker group compared to the controlled group. In an exploratory clinical trial evaluating the use of the subcutaneous formulation of golimumab in patients with severe persistent asthma, more patients treated with golimumab reported malignancies compared with control patients. The significance of this finding is unknown.

During the controlled portion of the Phase 3 trial in RA for golimumab, the incidence of malignancies other than lymphoma and NMSC per 100-patient-years of follow-up was 0.56 (95% CI: 0.01, 3.11) in the golimumab group compared with an incidence of 0 (95% CI: 0.00, 3.79) in the placebo group.

5.3 Congestive Heart Failure

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF-blockers, including golimumab products. Some cases had a fatal outcome. In several exploratory trials of other TNF-blockers in the treatment of CHF, there were greater proportions of TNF-blocker treated patients who had CHF exacerbations requiring hospitalization or increased mortality. Golimumab products have not been studied in patients with a history of CHF and IMMGOLIS INTRI should be used with caution in patients with CHF. If a decision is made to administer IMMGOLIS INTRI to patients with CHF, these patients should be closely monitored during therapy, and IMMGOLIS INTRI should be discontinued if new or worsening symptoms of CHF appear.

5.4 Demyelinating Disorders

Use of TNF-blockers, including golimumab products, has been associated with rare cases of new onset or exacerbation of central nervous system (CNS) demyelinating disorders, including multiple sclerosis (MS), and peripheral demyelinating disorders, including Guillain-Barré syndrome. Cases of central demyelination, MS, optic neuritis, and peripheral demyelinating polyneuropathy have rarely been reported in patients treated with golimumab products. Prescribers should exercise caution in considering the use of TNF-blockers, including IMMGOLIS INTRI, in patients with central or peripheral nervous system demyelinating disorders. Discontinuation of IMMGOLIS INTRI should be considered if these disorders develop.

5.5 Autoimmunity

Treatment with TNF blockers, including IMMGOLIS INTRI, may result in the formation of antinuclear antibodies (ANA). Rarely, treatment with TNF blockers, may result in the development of a lupus-like syndrome *[see Adverse Reactions (6.1)]*. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with IMMGOLIS INTRI, treatment should be discontinued.

5.6 Use with Abatacept

In controlled trials, the concurrent administration of another TNF-blocker and abatacept was associated with a greater proportion of serious infections than the use of a TNF-blocker alone; and the combination therapy, compared to the use of a TNF-blocker alone, has not demonstrated improved clinical benefit in the treatment of RA. Therefore, the combination of TNF-blockers, including IMMGOLIS INTRI, and abatacept is not recommended *[see Drug Interactions (7.2)]*.

5.7 Use with Anakinra

Concurrent administration of anakinra (an interleukin-1 antagonist) and another TNF-blocker was associated with a greater portion of serious infections and neutropenia and no additional benefits compared with the TNF-blocker alone. Therefore, the combination of anakinra with TNF-blockers, including IMMGOLIS INTRI, is not recommended *[see Drug Interactions (7.2)]*.

5.8 Switching Between Biological Disease Modifying Antirheumatic Drugs (DMARDs)

Care should be taken when switching from one biologic product to another biologic product since overlapping biological activity may further increase the risk of infection.

5.9 Hematologic Cytopenias

There have been reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anemia, and thrombocytopenia in patients receiving golimumab. Caution should be exercised when using

TNF-blockers, including IMMGOLIS INTRI, in patients who have or have had significant cytopenias.

5.10 Vaccinations/Therapeutic Infectious Agents

Live Vaccines

Avoid live vaccines in patients treated with IMMGOLIS INTRI. In patients receiving anti-TNF therapy, limited data are available on the response to live vaccination, or on the secondary transmission of infection by live vaccines. Use of live vaccines could result in clinical infections, including disseminated infections.

Administration of live vaccines to infants exposed to IMMGOLIS INTRI *in utero* is not recommended for 6 months following the mother's last IMMGOLIS INTRI infusion during pregnancy *[see Drug Interactions (7.3) and Use in Specific Populations (8.1)]*.

Whenever possible update immunizations prior to initiation of treatment with IMMGOLIS INTRI following current immunization guidelines for patients receiving immunosuppressive agents. Advise patients to discuss with the physician before seeking any immunizations.

Therapeutic Infectious Agents

Other uses of therapeutic infectious agents such as live attenuated bacteria (e.g., BCG bladder instillation for the treatment of cancer) could result in clinical infections, including disseminated infections. It is recommended that therapeutic infectious agents not be given concurrently with IMMGOLIS INTRI.

5.11 Hypersensitivity Reactions

In postmarketing experience, serious systemic hypersensitivity reactions (including anaphylaxis) have been reported following administration of the subcutaneous and intravenous formulations of golimumab products including IMMGOLIS INTRI. Hypersensitivity reactions including hives, pruritus, dyspnea, and nausea, were reported during infusion and generally within an hour after infusion. Some of these reactions occurred after the first administration of golimumab products. If an anaphylactic or other serious allergic reaction occurs, administration of IMMGOLIS INTRI should be discontinued immediately and appropriate therapy instituted.

6 ADVERSE REACTIONS

The most serious adverse reactions were:

- Serious Infections *[see Warnings and Precautions (5.1)]*
- Malignancies *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety data described below are based on one, randomized, double-blind, controlled Phase 3 trial in patients with RA receiving golimumab by intravenous infusion (Trial RA). The protocol included provisions for patients taking placebo to receive treatment with golimumab at Week 16 or Week 24 either by patient response (based on uncontrolled disease activity) or by design, so that adverse events cannot always be unambiguously attributed to a given treatment. Comparisons between placebo and golimumab were based on the first 24 weeks of exposure.

Trial RA included 197 control-treated patients and 463 golimumab-treated patients (which includes control-treated patients who switched to golimumab at Week 16). The proportion of patients who discontinued treatment due to adverse reactions in the controlled phase of Trial RA through Week 24 was 3.5% for golimumab-treated patients and 0.5% for placebo-treated patients. Upper respiratory tract infection was the most common adverse reaction reported in the trial through Week 24 occurring in 6.5% of golimumab-treated patients as compared with 7.6% of control-treated patients, respectively.

Infections

Serious infections observed in golimumab-treated patients included sepsis, pneumonia, cellulitis, abscess, opportunistic infections, tuberculosis (TB), and invasive fungal infections. Cases of TB included pulmonary and extrapulmonary TB. The majority of the TB cases occurred in countries with a high incidence rate of TB *[see Warnings and Precautions (5.1)]*.

In the controlled phase of Trial RA through Week 24, infections were observed in 27% of golimumab-treated patients compared with 24% of control-treated patients, and serious infections were observed in 0.9% of golimumab-treated patients and 0.0% of control-treated patients. Through Week 24, the incidence of serious infections per 100 patient-years of follow-up was 2.2 (95% CI 0.61, 5.71) for the golimumab group, and 0 (0.00, 3.79) for the placebo group. In the controlled and uncontrolled portions of Trial RA, 958 total patient-years of follow-up with a median follow-up of approximately 92 weeks, the incidence per 100 patient-years of all serious infections was 4.07 (95% CI: 2.90, 5.57) in patients receiving golimumab *[see Warnings and Precautions (5.1)]*. In the controlled and uncontrolled portions of Trial RA, in golimumab-treated patients, the incidence of active TB per 100 patient-years was 0.31 (95% CI: 0.06; 0.92) and the incidence of other opportunistic infections per 100 patient-years was 0.42 (95% CI: 0.11, 1.07).

Malignancies

One case of malignancy other than lymphoma and NMSC with golimumab was reported through Week 24 during the controlled phase of Trial RA. In the controlled and uncontrolled portions through approximately 92 weeks, the incidence of malignancies per 100 patient-years, other than lymphoma and NMSC, in golimumab-treated patients was 0.31 (95% CI: 0.06, 0.92) and the incidence of NMSC was 0.1 (95% CI: 0.00, 0.58).

Liver Enzyme Elevations

There have been reports of severe hepatic reactions including acute liver failure in patients receiving TNF-blockers.

In the controlled phase of Trial RA, through Week 24, ALT elevations ≥ 5 x ULN occurred in 0.8% of golimumab-treated patients and 0% of control-treated patients and ALT elevations ≥ 3 x ULN occurred in 2.3% of golimumab-treated patients and 2.5% of control-treated patients.

Since many of the patients in the Phase 3 trials were also taking medications that cause liver enzyme elevations (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], MTX, or isoniazid prophylaxis), the relationship between golimumab and liver enzyme elevation is not clear.

Autoimmune Disorders and Autoantibodies

At Week 20 in Trial RA, 17% of golimumab-treated patients and 13% of control patients were newly antinuclear antibody (ANA)-positive. Of these patients, one golimumab-treated patient and no control-treated patients had newly positive anti-dsDNA antibodies *[see Warnings and Precautions (5.5)]*.

Administration Reactions

In the controlled phase of Trial RA through Week 24, 1.1% of golimumab infusions were associated with an infusion reaction compared with 0.2% of infusions in the control group. The most common infusion reaction in golimumab-treated patients was rash. No serious infusion reactions were reported.

Other Adverse Reactions

Table 1 summarizes the adverse drug reactions that occurred at a rate of at least 1% in the golimumab + MTX group with a higher incidence than in the placebo + MTX group during the controlled period of Trial RA through Week 24.

Table 1: Adverse Drug Reactions Reported by ≥ 1% of Golimumab-Treated Patients and with a Higher Incidence than Placebo-Treated Patients in Trial RA through Week 24

	Placebo + MTX	Golimumab + MTX
Patients treated	197	463
Adverse Reaction		
Infections and infestations		
Upper respiratory tract infection (such as upper respiratory tract infection, nasopharyngitis, pharyngitis, laryngitis, and rhinitis)	12%	13%
Viral infections (such as influenza and herpes)	3%	4%
Bacterial infections	0%	1%
Bronchitis	1%	3%
Vascular disorders		
Hypertension	2%	3%
Skin and subcutaneous disorders		
Rash	1%	3%
General disorders and administration site conditions		
Pyrexia	1%	2%
Blood and lymphatic disorders		
Leukopenia	0%	1%

Other and Less Common Clinical Trial Adverse Drug Reactions

Adverse drug reactions that do not appear in Table 1 or that occurred < 1% in golimumab-treated patients during Trial RA through Week 24 that do not appear in the Warnings and Precautions section included the following events listed by system organ class:

Infections and infestations: Superficial fungal infection, sinusitis, abscess, lower respiratory tract infection (pneumonia), pyelonephritis

Investigations: Alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased, neutrophil count decreased

Nervous system disorders: Dizziness, paresthesia

Gastrointestinal disorders: Constipation

6.2 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other

studies, including those of golimumab or of other golimumab products.

Using an enzyme immunoassay (EIA) method, antibodies to golimumab were detected in 13 (3%) golimumab-treated patients following IV administration of golimumab in combination with MTX through Week 24 of Trial RA, of which all were neutralizing antibodies.

A drug-tolerant enzyme immunoassay (drug-tolerant EIA) method for detecting antibodies to golimumab was developed and validated. This method is approximately 16-fold more sensitive than the original EIA method with less interference from golimumab in serum. Through approximately 6 months, the incidence of antibodies to golimumab with the drug-tolerant EIA method for Trials RA, was 21%. Where tested, approximately one-third to one-half were neutralizing.

Patients with RA who developed antibodies to golimumab generally had lower trough steady-state serum concentrations of golimumab *[see Clinical Pharmacology (12.3)]*.

6.3 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of golimumab products. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to golimumab product exposure:

General Disorders and Administration Site Conditions: Infusion-related reactions *[see Warnings and Precautions (5.11)]*

Neoplasm benign and malignant: Melanoma, Merkel cell carcinoma *[see Warnings and Precautions (5.2)]*

Immune system disorders: Serious systemic hypersensitivity reactions (including anaphylactic reaction) *[see Warnings and Precautions (5.11)]*, sarcoidosis

Respiratory, thoracic and mediastinal disorders: Interstitial lung disease

Skin and subcutaneous tissue disorders: Skin exfoliation, lichenoid reactions, bullous skin reactions

7 DRUG INTERACTIONS

7.1 Methotrexate

IMMGOLIS INTRI should be used with MTX for the treatment of RA *[see Clinical Studies (14.1)]*. Following IV administration, concomitant administration of methotrexate decreases the clearance of golimumab by approximately 9% based on population pharmacokinetics (PK) analysis. In addition, concomitant administration of methotrexate decreases the golimumab clearance by reducing the development of antibodies to golimumab.

7.2 Biologic Products for RA

An increased risk of serious infections has been seen in clinical RA studies of other TNF-blockers used in combination with anakinra or abatacept, with no added benefit; therefore, use of IMMGOLIS INTRI with other biologic products, including abatacept or anakinra, is not recommended *[see Warnings and Precautions (5.6 and 5.7)]*. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF-blocker. The concomitant use of IMMGOLIS INTRI with biologics approved to treat RA is not recommended because of the possibility of an increased risk of infection.

7.3 Live Vaccines/Therapeutic Infectious Agents

Live vaccines should not be given concurrently with IMMGOLIS INTRI *[see Warnings and Precautions (5.10)]*.

Therapeutic infectious agents should not be given concurrently with IMMGOLIS INTRI *[see Warnings and Precautions (5.10)]*.

Infants born to women treated with golimumab products during their pregnancy may be at increased risk of infection for up to 6 months. Administration of live vaccines to infants exposed to IMMGOLIS INTRI *in utero* is not recommended for 6 months following the mother's last IMMGOLIS INTRI infusion during pregnancy *[see Warnings and Precautions (5.10), Use in Specific Populations (8.1)]*.

7.4 Cytochrome P450 Substrates

The formation of CYP450 enzymes may be suppressed by increased levels of cytokines (e.g., TNFα) during chronic inflammation. Therefore, it is expected that for a molecule that antagonizes cytokine activity, such as golimumab, the formation of CYP450 enzymes could be normalized. Upon initiation or discontinuation of IMMGOLIS INTRI in patients being treated with CYP450 substrates with a narrow therapeutic index, monitoring of the effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) is recommended and the individual dose of the drug product may be adjusted as needed.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from postmarketing case reports with golimumab use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. An observational study of northern European births observed similar unadjusted rates of major birth defects in infants exposed *in utero* to golimumab compared to no treatment or nonbiologic systemic therapy. However, this study had important limitations (*see Data*).

Monoclonal antibodies, such as golimumab products, are transported across the placenta during the third trimester of pregnancy and may affect immune response in the *in utero* exposed infant. There are clinical considerations for the use of golimumab products in pregnant women *[see Clinical Considerations]*. In an animal reproductive study, golimumab administered by the subcutaneous route to pregnant monkeys, during the period of organogenesis, at doses that produced exposures approximately 200 times the maximum recommended human dose (MRHD) had no adverse fetal effects.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and of miscarriage is 15-20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Golimumab products cross the placenta during pregnancy. Another TNF-blocking monoclonal antibody administered during pregnancy was detected for up to 6 months in the serum of infants. Consequently, these infants may be at increased risk of infection. Administration of live vaccines to

infants exposed to IMMGOLIS INTRI *in utero* is not recommended for 6 months following the mother's last IMMGOLIS INTRI infusion during pregnancy *[see Warnings and Precautions (5.10) and Drug Interactions (7.3)]*.

Data

Human Data

An observational, exposure-based, cohort study based on data from the Swedish, Danish, and Finnish Medical Birth Registers conducted between 2006-2020 (Sweden and Denmark) and 2006-2019 (Finland) compared the risk of major birth defects in 134 live-born infants exposed to golimumab (116 from women treated for rheumatic conditions, 18 from women treated for ulcerative colitis) to no treatment or nonbiologic systemic therapy. The unadjusted rate of major birth defects in infants exposed in utero was similar across all groups. However, this study had important limitations such as a small number of pregnant women exposed to golimumab, a wide exposure ascertainment window, and incomplete risk adjustment for potential confounders.

Animal Data

In an embryofetal developmental toxicology study in which pregnant cynomolgus monkeys were treated with golimumab during the period of organogenesis from gestation days (GD) 20 to 51, exposures up to 200 times greater than the exposure at the MRHD (on an area under the curve (AUC) basis with maternal subcutaneous doses up to 50 mg/kg twice weekly) produced no evidence of fetal malformations or embryotoxicity. There was no evidence of maternal toxicity. Umbilical cord blood samples collected at the end of the second trimester showed that fetuses were exposed to golimumab during gestation.

In a pre- and postnatal developmental study in which pregnant cynomolgus monkeys were treated with golimumab from gestation day 50 to postpartum day 33, maximal drug concentrations up to 33 times greater than that found with the MRHD (on a maximum blood concentration (C_{max}) basis at steady-state with maternal subcutaneous doses up to 50 mg/kg twice weekly) were not associated with any evidence of developmental defects in infants. There was no evidence of maternal toxicity. Golimumab was present in fetal serum at the end of the second trimester and in neonatal serum from the time of birth and for up to 6 months postpartum.

8.2 Lactation

Risk Summary

There is no information regarding the presence of golimumab products in human milk, the effects on breastfed infants, or the effects on milk production. Maternal IgG is known to be present in human milk. Golimumab is present in the milk of lactating cynomolgus monkeys (*see Data*). If golimumab products are transferred into human milk, the effects of local exposure in the gastrointestinal tract and potential limited systemic exposure in the infant to golimumab products are unknown. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for golimumab and any potential adverse effects on the breast-fed infants from IMMGOLIS INTRI, or from the underlying maternal condition.

Data

In the pre- and postnatal development study in cynomolgus monkeys in which golimumab was administered subcutaneously during pregnancy and lactation, golimumab was detected in the breast milk at concentrations that were approximately 400-fold lower than the maternal serum concentrations.

8.4 Pediatric Use

A pediatric assessment for IMMGOLIS INTRI demonstrates that IMMGOLIS INTRI is safe and effective for pediatric patients in an indication for which Simponi Aria® (golimumab) is approved. However, IMMGOLIS INTRI is not approved for such indication due to marketing exclusivity for Simponi Aria (golimumab).

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with golimumab products and other TNF-blocking agents *[see Warnings and Precautions (5.2)]*.

8.5 Geriatric Use

In Trial RA, the number of patients ages 65 or older was too small to make comparisons with younger golimumab-treated patients. Because there is a higher incidence of infections in the geriatric population in general, caution should be used in treating geriatric patients with IMMGOLIS INTRI.

10 OVERDOSAGE

In a clinical study, 5 patients received single infusions of up to 1000 mg of golimumab without serious adverse reactions or other significant reactions.

11 DESCRIPTION

Golimumab-sldi is a human IgG1κ monoclonal antibody specific for human tumor necrosis factor alpha (TNFα) that exhibits multiple glycoforms with molecular masses of approximately 150 to 151 kilodaltons. Golimumab-sldi was created using recombinant DNA technology, resulting in an antibody with human-derived antibody variable and constant regions. Golimumab-sldi is produced by a Chinese Hamster Ovary (CHO) cell line and is purified by a series of steps that includes measures to inactivate and remove viruses.

The IMMGOLIS INTRI (golimumab-sldi) injection is a sterile solution of the golimumab-sldi antibody supplied in a 4-mL glass vial for intravenous infusion.

IMMGOLIS INTRI is a preservative-free, clear, colorless to light yellow solution with a pH of approximately 5.5. IMMGOLIS INTRI is not made with natural rubber latex. Each 4-mL vial of IMMGOLIS INTRI contains 50 mg golimumab-sldi, histidine (1.60 mg), L-histidine monohydrochloride monohydrate (6.20 mg), polysorbate 80 (0.80 mg), trehalose (307.62 mg), and water for injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Golimumab products are human monoclonal antibodies that binds to both the soluble and transmembrane bioactive forms of human TNFα. This interaction prevents the binding of TNFα to its receptors, thereby inhibiting the biological activity of TNFα (a cytokine protein). There was no evidence of the golimumab product antibodies binding to other TNF superfamily ligands; in particular, the golimumab product antibodies did not bind or neutralize human lymphotoxin. Golimumab products did not lyse human monocytes expressing transmembrane TNF in the presence of complement or effector cells.

Elevated TNFα levels in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis. TNFα is an important mediator of the articular inflammation that is characteristic of these diseases. Golimumab

modulated the *in vitro* biological effects mediated by TNF in several bioassays, including the expression of adhesion proteins responsible for leukocyte infiltration (E-selectin, ICAM-1 and VCAM-1) and the secretion of proinflammatory cytokines (IL-6, IL-8, G-CSF and GM-CSF). The clinical relevance of these findings is unknown.

12.2 Pharmacodynamics

Following treatment with golimumab in patients with RA, decreases from baseline were observed in tissue inhibitor of metalloproteinase-1 (TIMP-1), matrix metalloproteinase-1 (MMP-1), matrix metalloproteinase-3 (MMP-3), resistin, interleukin-6 (IL-6), macrophage inflammatory protein-1 (MIP-1b), vascular endothelial growth factor (VEGF), serum amyloid A (SAA), S100A12, and high sensitivity C-Reactive protein (hsCRP). Conversely, increases from baseline were observed in tartrate-resistant acid phosphatase (TRAP-5b). The clinical relevance of this information is not known.

12.3 Pharmacokinetics

Golimumab exhibited approximately dose-proportional pharmacokinetics in patients with RA over the dose range of 0.1 to 10.0 mg/kg following a single intravenous dose.

Absorption

Following a single intravenous administration of 2 mg/kg golimumab, a mean C_{max} of 44.4 ± 11.3 mcg/mL was observed in patients with RA. Data directly comparing 2 mg/kg intravenous administration and 50 mg subcutaneous administration are not available.

Distribution

Following a single intravenous administration of 2 mg/kg golimumab, the mean volume of distribution was estimated to be 115 ± 19 mL/kg in healthy subjects, and 151 ± 61 mL/kg in patients with RA. The volume of distribution of golimumab may indicate that golimumab is distributed primarily in the circulatory system with limited extravascular distribution.

Elimination

Following a single intravenous administration of 2 mg/kg golimumab, the systemic clearance of golimumab was estimated to be 6.9 ± 2.0 mL/day/kg in healthy subjects and 7.6 ± 2.0 mL/day/kg in patients with RA. The mean terminal half-life was estimated to be 12 ± 3 days in healthy subjects and the mean terminal half-life in RA patients was 14 ± 4 days.

Multiple Doses

When 2 mg/kg golimumab was administered intravenously to patients with RA at weeks 0, 4 and every 8 weeks thereafter, serum concentrations reached steady-state by Week 12. With concomitant use of MTX, treatment with 2 mg/kg golimumab every 8 weeks resulted in a mean steady-state trough serum concentration of approximately 0.4 ± 0.4 mcg/mL in patients with active RA.

Patients with RA who developed antibodies to golimumab generally had lower trough steady-state serum concentrations of golimumab *[see Adverse Reactions (6.2)]*.

Specific Populations

No formal study of the effect of renal or hepatic impairment on the PK of golimumab products was conducted.

Body Weight

Following intravenous administration, patients with higher body weight tended to have slightly

higher serum golimumab concentrations than patients with lower body weights when golimumab was administered on a mg/kg (body weight) basis. However, based on population PK analysis, there were no clinically relevant differences in golimumab exposure following intravenous administration of 2 mg/kg golimumab in adult patients across a range of different body weights.

Drug Interaction Studies

Specific drug interaction studies have not been conducted with golimumab products.

Population PK analysis indicated that concomitant use of MTX, NSAIDs, oral corticosteroids, or sulfasalazine (SSZ) did not significantly influence the clearance of golimumab following IV administration.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies of golimumab products have not been conducted to evaluate its carcinogenic potential. Mutagenicity studies have not been conducted with golimumab products. A fertility study conducted in mice using an analogous anti-mouse TNFα antibody administered by the intravenous route at doses up to 40 mg/kg once per week showed no impairment of fertility.

14 CLINICAL STUDIES

14.1 Rheumatoid Arthritis

The efficacy and safety of golimumab were evaluated in one multicenter, randomized, double-blind, controlled trial (Trial RA, NCT00973479) in 592 patients ≥ 18 years of age with moderately to severely active RA despite concurrent MTX therapy and had not previously been treated with a biologic TNF-blocker. Patients were diagnosed according to the American College of Rheumatology (ACR) criteria, at least 3 months prior to administration of study agent and were required to have at least 6 swollen and 6 tender joints. Patients were randomized to receive either golimumab 2 mg/kg (N=395) or placebo (N=197) over a 30-minute intravenous infusion at Weeks 0, 4 and every 8 weeks thereafter in addition to their weekly maintenance MTX dose (15-25 mg). All patients receiving placebo + MTX received golimumab + MTX after Week 24, but the trial remained blinded until all patients had completed 108 weeks of treatment. Efficacy data were collected and analyzed through Week 52. Patients were allowed to continue stable doses of concomitant low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day) and/or NSAIDs. The use of other DMARDs including cytotoxic agents or other biologics was prohibited.

The primary endpoint in Trial RA was the percentage of patients achieving an ACR 20 response at Week 14. In Trial RA, the majority of subjects were women (82%) and were Caucasian (80%) with a median age of 52 years and a median weight of 70 kg. Median disease duration was 4.7 years, and 50% of the patients used at least one DMARD other than MTX in the past. At baseline, 81% of patients received concomitant NSAIDs and 81% of patients received low-dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day). The median baseline DAS28-CRP was 5.9 and the median van der Heijde-Sharp score at baseline was 28.5.

Clinical Response

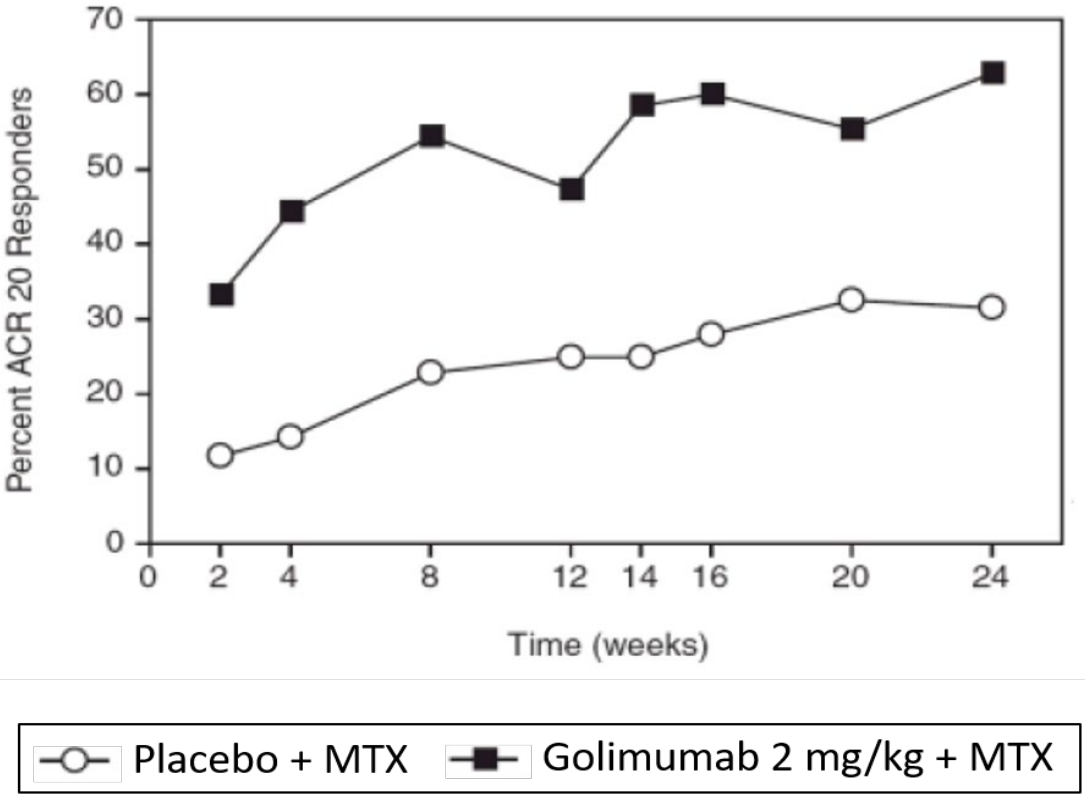
A greater percentage of patients treated with the combination of golimumab + MTX achieved ACR 20 at Week 14 and ACR 50 at Week 24 versus patients treated with the placebo + MTX as shown in Table 2. The percent of patients achieving ACR 20 responses by visit for Trial RA is shown in Figure 1.

Table 2: Trial RA – Proportion of Patients with an ACR Response

Trial RA Active RA, despite MTX			
	Placebo + MTX	**Golimumab + MTX**	**95% CI[a]**
N[b]	197	395	
ACR 20			
Week 14	25%	59%	25.9, 41.4
Week 24	32%	63%	23.3, 39.4
ACR 50			
Week 14	9%	30%	15.3, 27.2
Week 24	13%	35%	15.1, 28.4
ACR 70			
Week 14	3%	12%	5.3, 13.4
Week 24	4%	18%	8.8, 18.1

[a] For difference in proportions.
[b] N reflects randomized patients.

Figure 1: Trial RA – Percent of Patients Achieving ACR 20 Response Over Time: Randomized Patients



The analysis is based on the intent-to-treat population. Last observation carried forward was performed for missing data. Patients who discontinued treatment due to lack of efficacy were counted as non-responders, as were patients who started prohibited medication or failed to achieve at least a 10% improvement in joint counts at Week 16.

The improvement in all components of the ACR response criteria for the golimumab + MTX group was greater compared to the placebo + MTX group in Trial RA as shown in Table 3.

Table 3: Trial RA – Components of ACR Response at Week 14

Trial RA Active RA, despite MTX		
	Placebo + MTX	**Golimumab + MTX**
N[a]	197	395
Number of swollen joints (0-66)		
Baseline	15	15
Week 14	11	6
Number of tender joints (0-68)		
Baseline	26	26
Week 14	20	13
Patient's assessment of pain (0-10)		
Baseline	6.5	6.5
Week 14	5.6	3.9
Patient's global assessment of disease activity (0-10)		
Baseline	6.5	6.5
Week 14	5.5	4.0
Physician's global assessment of disease activity (0-10)		
Baseline	6.3	6.2
Week 14	4.9	3.1
HAQ score (0-3)		
Baseline	1.6	1.6
Week 14	1.4	1.1
CRP (mg/dL) (0-1)		
Baseline	2.2	2.8
Week 14	1.8	0.9

Note: All values are means.

[a] N reflects randomized patients; actual number of patients evaluable for each endpoint may vary.

At Week 14, a greater proportion of patients treated with golimumab + MTX achieved a low level of disease activity as measured by a DAS28-CRP less than 2.6 compared with the placebo + MTX group (15% compared to 5%; 95% CI for difference [6.3%, 15.5%]).

Radiographic Response

In Trial RA, structural joint damage was assessed radiographically and expressed as a change in van der Heijde-Modified Sharp Score (vdH-S) and its components, the erosion score and Joint Space Narrowing (JSN) score, at Week 24 compared to baseline. The golimumab + MTX treatment group inhibited the progression of structural damage compared with placebo + MTX, as assessed by total vdH-S score as shown in Table 4.

Table 4: Trial RA – Radiographic Change From Baseline at Week 24

	Placebo + MTX (N=197)[a]	Golimumab + MTX (N=395)[a,b]
	Mean	**Mean**
Change Total vdH-S Score	1.1	0.03*
Change Erosion Score	0.5	-0.1
Change JSN Score	0.6	0.1

[a] N reflects randomized patients.
[b] p-value is displayed only for the major secondary endpoint.
* $p \leq 0.001$.

At Week 24, a greater proportion of patients in the golimumab + MTX group (71%) had no progression of structural damage (change in the total vdH-S score ≤ 0), compared to 57% of patients in the placebo + MTX group. At Week 52, the mean change from baseline in total vdH-S score was 1.2 in patients originally randomized to placebo + MTX who crossed over to golimumab + MTX at Week 16 or Week 24, and 0.1 in patients originally randomized to golimumab + MTX who remained on active treatment.

Physical Function Response in Patients with RA

Physical function was assessed by the disability index of the Health Assessment Questionnaire (HAQ-DI). At Week 14, the golimumab + MTX group showed greater mean improvement in the HAQ-DI compared with placebo + MTX (0.5 compared to 0.2; 95% CI for difference [0.2, 0.4]).

Other Health-Related Outcomes

General health status was assessed by the 36-item Short Form Health Survey (SF-36). In Trial RA, patients receiving golimumab + MTX demonstrated greater improvement from baseline compared with placebo + MTX in physical component summary (PCS), mental component summary (MCS) scores and in all 8 domains of the SF-36.

Fatigue was assessed by the Functional Assessment of Chronic Illness Therapy-Fatigue score (FACIT-F) in Trial RA. Treatment with golimumab resulted in improvement in fatigue as measured by FACIT-F.

16 HOW SUPPLIED/STORAGE AND HANDLING

IMMGOLIS INTRI® (golimumab-sldi) injection is a clear, colorless to light yellow solution available in packs of 1 vial NDC 69448-029-64.

Vial

Each single-dose vial contains 50 mg of IMMGOLIS INTRI per 4 mL of solution.

Storage and Handling

Refrigerate IMMGOLIS INTRI at 36ºF to 46ºF (2ºC to 8ºC) and protect from light. Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake.

If needed, IMMGOLIS INTRI may be stored at room temperature up to 77ºF (25ºC) for a maximum single period of 15 days in the original carton to protect from light. Once IMMGOLIS INTRI has been stored at room temperature, do not return the product to the refrigerator. If not used within 15 days at room temperature, discard IMMGOLIS INTRI.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Advise patients of the potential benefits and risks of IMMGOLIS INTRI. Instruct patients to read the Medication Guide before starting IMMGOLIS INTRI therapy and to read it each time the prescription is renewed.

Infections

Inform patients that IMMGOLIS INTRI may lower the ability of their immune system to fight infections. Instruct the patient of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis, invasive fungal infections, and hepatitis B reactivation.

Malignancies

Patients should be counseled about the risk of lymphoma and other malignancies while receiving IMMGOLIS INTRI. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

Other Medical Conditions

Advise patients to report any signs of new or worsening medical conditions such as congestive heart failure, demyelinating disorders, autoimmune diseases, liver disease, cytopenias, or psoriasis.

Vaccinations

Inform patients that because IMMGOLIS INTRI may lower the ability of their immune system to fight infections, they should avoid live vaccines. Inform pregnant patients receiving IMMGOLIS INTRI that their infants should not receive live vaccines for 6 months following the last infusion of IMMGOLIS INTRI during pregnancy. Advise patients and infants of women who received IMMGOLIS INTRI during pregnancy to consult a physician before receiving any immunizations.

Manufactured by:
Accord BioPharma, Inc.
8041 Arco Corporate Drive,
Suite 200, Raleigh, NC 27617 USA
US License No. 2105

MEDICATION GUIDE
IMMGOLIS INTRI™ (im-goe-lis-in-tree)
(golimumab-sldi)
injection, for intravenous use

What is the most important information I should know about IMMGOLIS INTRI?

IMMGOLIS INTRI is a medicine that affects your immune system. IMMGOLIS INTRI can lower the ability of your immune system to fight infections. Some people have serious infections while receiving golimumab products, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that spread throughout their body. Some people have died from these serious infections.

- Your doctor should test you for TB and hepatitis B before starting BRANDNAME.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with IMMGOLIS INTRI. You should not start receiving IMMGOLIS INTRI if you have any kind of infection unless your doctor tells you to.

Before receiving IMMGOLIS INTRI, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
    - fever, sweat, or chills
    - muscle aches
    - cough
    - shortness of breath
    - blood in phlegm
    - weight loss
    - warm, red, or painful skin or sores on your body
    - diarrhea or stomach pain
    - burning when you urinate or urinate more often than normal
    - feel very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live, have lived, or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may happen or become more severe if you use IMMGOLIS INTRI. Ask your doctor if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B.
- use the medicine ORENCIA (abatacept), KINERET (anakinra), ACTEMRA (tocilizumab) or RITUXAN (rituximab).

After receiving IMMGOLIS INTRI, call your doctor right away if you have any symptoms of an infection. IMMGOLIS INTRI can make you more likely to get infections or make worse any infection that you have.

Cancer

- For children and adults receiving Tumor Necrosis Factor (TNF)-blocker medicines, including IMMGOLIS INTRI, the chances of getting cancer may increase.
- There have been cases of unusual cancers in children and teenage patients receiving TNF-blocking agents.
- People with inflammatory diseases, including rheumatoid arthritis (RA), especially those with very active disease, may be more likely to get lymphoma.
- Some people receiving TNF-blockers, like IMMGOLIS INTRI, developed a rare type of cancer called hepatosplenic T- cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men. Also, most people were being treated for Crohn's disease or ulcerative colitis with a TNF blocker and another medicine called azathioprine or 6-mercaptopurine, (6-MP).
- Some people treated with golimumab products developed skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with IMMGOLIS INTRI, tell your doctor.
- You should see your doctor periodically for skin examinations, especially if you have a history of skin cancer.

What is IMMGOLIS INTRI?

IMMGOLIS INTRI is a prescription medicine called a TNF-blocker. IMMGOLIS INTRI is used to treat:

- adults with the medicine methotrexate (MTX) to treat moderately to severely active RA.

What should I tell my doctor before starting treatment with IMMGOLIS INTRI?

See "**What is the most important information I should know about IMMGOLIS INTRI?**".

Before starting IMMGOLIS INTRI, tell your doctor about all your medical conditions, including if you:

- have an infection.
- have or have had lymphoma or any other type of cancer.
- have or have had heart failure.
- have or have had a condition that affects your nervous system, such as multiple sclerosis or Guillain-Barré syndrome.
- have a skin problem called psoriasis.
- have recently received or are scheduled to receive a vaccine. People receiving IMMGOLIS INTRI should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer). People receiving IMMGOLIS INTRI can receive non-live vaccines.
- have a baby and you were receiving IMMGOLIS INTRI during your pregnancy. Tell your baby's doctor before your baby receives any vaccine. Your baby may have an increased chance of getting an infection for up to 6 months after birth.
- are pregnant or plan to become pregnant. It is not known if IMMGOLIS INTRI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if IMMGOLIS INTRI passes into your breast milk. You and your doctor should decide if you will receive IMMGOLIS INTRI or breastfeed.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially, tell your doctor if you:

- use ORENCIA (abatacept) or KINERET (anakinra). You should not receive IMMGOLIS INTRI while you are also receiving ORENCIA (abatacept) or KINERET (anakinra).
- use other TNF-blocker medicines, including REMICADE (infliximab), HUMIRA (adalimumab), ENBREL (etanercept), or CIMZIA (certolizumab pegol).
- receive RITUXAN (rituximab) or ACTEMRA (tocilizumab).

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Keep a list of all your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I receive IMMGOLIS INTRI?

- IMMGOLIS INTRI is prepared and given by a healthcare provider through a needle placed in your vein (infusion). The infusion is usually given in your arm and should take 30 minutes.
- Your doctor will decide how much IMMGOLIS INTRI you will receive. Your usual schedule for receiving IMMGOLIS INTRI after your first treatment should be:
  - 4 weeks after your first treatment
  - every 8 weeks after that
- If you miss an appointment to receive IMMGOLIS INTRI, make another appointment as soon as possible.

What are the possible side effects of IMMGOLIS INTRI?

IMMGOLIS INTRI can cause serious side effects, including:

See "**What is the most important information I should know about IMMGOLIS INTRI?**"

Serious Infections.

- Some patients have an increased chance of getting serious infections while receiving IMMGOLIS INTRI. These serious infections include TB and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients die from these infections. If you get an infection while receiving treatment with IMMGOLIS INTRI your doctor will treat your infection and may need to stop your IMMGOLIS INTRI treatment. Tell your doctor right away if you have any of the following signs of an infection while receiving or after receiving IMMGOLIS INTRI:
  - a fever
  - feel very tired
  - have a cough
  - have flu-like symptoms
  - warm, red, or painful skin
- Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with IMMGOLIS INTRI and during

treatment with IMMGOLIS INTRI. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you are receiving IMMGOLIS INTRI. People who had a negative TB skin test before receiving golimumab products have developed active TB. Tell your doctor if you have any of the following symptoms while receiving or after receiving IMMGOLIS INTRI:

- cough that does not go away
- low grade fever
- weight loss
- loss of body fat and muscle (wasting)

Hepatitis B infection in people who carry the virus in their blood. If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use IMMGOLIS INTRI. Your doctor should do blood tests before you start treatment with IMMGOLIS INTRI and while you are receiving IMMGOLIS INTRI.

- Tell your doctor if you have any of the following symptoms of a possible hepatitis B infection:
  - feel very tired
  - dark urine
  - skin or eyes look yellow
  - little or no appetite
  - vomiting
  - muscle aches
  - clay-colored bowel movements
  - fevers
  - chills
  - stomach discomfort
  - skin rash

Heart failure, including new heart failure or worsening of heart failure that you already have can happen in people who use TNF-blocker medicines, including IMMGOLIS INTRI. If you develop new or worsening heart failure with IMMGOLIS INTRI, you may need to be treated in a hospital, and it may result in death.

- If you have heart failure before starting IMMGOLIS INTRI, your condition should be watched closely during treatment with IMMGOLIS INTRI.
- Call your doctor right away if you get new or worsening symptoms of heart failure during treatment with IMMGOLIS INTRI (such as shortness of breath or swelling of your lower legs or feet, or sudden weight gain).

Nervous System Problems. Rarely, people receiving TNF-blocker medicines, including IMMGOLIS INTRI, have nervous system problems such as multiple sclerosis or Guillain-Barré syndrome. Tell your doctor right away if you get any of these symptoms:

- vision changes
- weakness in your arms or legs
- numbness or tingling in any part of your body

Immune System Problems. Rarely, people receiving TNF-blocker medicines have developed symptoms that are like the symptoms of lupus. Tell your doctor if you have any of these symptoms:

- a rash on your cheeks or other parts of the body
- sensitivity to the sun
- new joint or muscle pains
- becoming very tired
- chest pain or shortness of breath
- swelling of the feet, ankles, or legs

Liver Problems. Liver problems can happen in people who receive TNF-blocker medicines, including IMMGOLIS INTRI. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms:

- feel very tired
- skin or eyes look yellow
- poor appetite or vomiting
- pain on the right side of your stomach (abdomen)

Blood Problems. Low blood counts have been seen with golimumab products. Your body may not make enough blood cells that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding easily, or looking pale. Your doctor will check your blood counts before and during treatment with IMMGOLIS INTRI.

Allergic Reactions. Allergic reactions can happen in people who receive TNF-blocker medicines, including IMMGOLIS INTRI. Some reactions may be serious and can be life-threatening. Some of these reactions can happen after receiving your first dose of IMMGOLIS INTRI. Call your doctor right away if you have any of these symptoms of an allergic reaction:

- hives
- swollen face
- breathing trouble
- chest pain

The most common side effects of IMMGOLIS INTRI include:

- upper respiratory infection (runny nose, sore throat, and hoarseness or laryngitis)
- abnormal liver tests
- decreased blood cells that fight infection
- viral infections, such as flu and cold sores in the mouth
- bronchitis

- high blood pressure
- rash

These are not all of the possible side effects of IMMGOLIS INTRI.

Tell your doctor about any side effect that bothers you or does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMMGOLIS INTRI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your doctor or pharmacist for information about IMMGOLIS INTRI that is written for health professionals.

What are the ingredients in IMMGOLIS INTRI?

Active ingredient: golimumab-sldi.

Inactive ingredients: histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, trehalose, and water for injection. IMMGOLIS INTRI is preservative-free and is not made with natural rubber latex.

Manufactured by: Accord BioPharma, Inc. 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617 USA

US License No. 2105

For more information go to www.immgolisintri.com.com or call 1-866-941-7875.

This Medication Guide has been approved by the U.S. Food and Drug Administration Issued: 05/2026

152 mm

63 mm

LOT : XXXXXXXXXXX
EXP : YYYY-MM-DD

IMMGOLIS™

(golimumab-sldi)
Injec ion

50 mg/0.5 mL

For Subcutaneous injection.

Accord BioPharma, Inc.
8041 Arco Corporate Drive, Suite 200
Raleigh, NC 27617 USA U.S. License No.: 2105

accord™

NDC 69448-**028**-63
℞ Only

0.5 mL single-dose prefilled syringe

Store refrigerated at 36°F to 46°F (2°C to 8°C)
to protect from light.
Do not shake. Do not freeze.

Recommended Dosage:
See prescribing information.

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(b) (4)

Representation of batch prompts and data printed black online

2D

GTIN : XXXXXXXXXXXXX
S/N : XXXXXXXXXX
LOT : XXXXXXXXXX
EXP : YYYY-MM-DD

2D Code to incorporate:
GTIN(XXXXXXXXXXXXX)
S/N(XXXXXXXXXX)
Lot(XXXXXXXXXX)
EXP(YYYY-MM-DD)

FPO

FPO

accord™

FOR SUBCUTANEOUS INJECTION

Sterile solution in a single-dose prefilled syringe.
No preservative.
Discard unused portion.
Recommended Dosage: See prescribing information.

This product contains dry natural rubber.

NDC 69448-**028**-63

IMMGOLIS™
(golimumab-sldi)
Injec ion

50 mg/0.5 mL

0.5 mL single-dose prefilled syringe

FOR SUBCUTANEOUS INJECTION

℞ Only

Manufactured at:
Bio-Thera Solutions, Ltd.
155 Yaotianhe Street,
Huangpu District, Guangzhou,
Guangdong, China, 511356

Manufactured by:
Accord BioPharma, Inc.
8041 Arco Corporate Dr., Suite 200
Raleigh, NC 27617 USA
U.S. License No: 2105

IMMGOLIS™
(golimumab-sldi)
Injec ion

50 mg/0.5 mL

0.5 mL single-dose prefilled syringe

℞ Only

IMMGOLIS™
(golimumab-sldi)
Injec ion

50 mg/0.5 mL

0.5 mL single-dose prefilled syringe

NDC 69448-**028**-63

IMMGOLIS™
(golimumab-sldi)
Injec ion

50 mg/0.5 mL

0.5 mL single-dose prefilled syringe

FOR SUBCUTANEOUS INJECTION

accord™

Sterile solution in single-dose prefilled syringe. No preservative.
Store refrigerated at 36°F to 46°F (2°C to 8°C) and keep in carton to protect from light. Do not shake. Do not freeze.
IMMGOLIS may be stored at room temperature up to 77°F (25°C) for a maximum single period of 15 days in the original carton to protect from light. Do not return it to the refrigerator. Discard if not used within 15 days at room temperature. Write date removed from the refrigerator __/__/____.
Keep out of reach of children.

Each 0.5 mL single-dose prefilled syringe contains:
50 mg golimumab-sldi, histidine (0.14 mg), L-histidine monohydrochloride monohydrate (0.86 mg), polysorbate 80 (0.10 mg), trehalose (38.453 mg), and water for injection.

Recommended Dosage: See prescribing Information.

3 69448 02863 3

℞ Only

IMMGOLIS™
(golimumab-sldi)
Injec ion

50 mg/0.5 mL

0.5 mL single-dose prefilled syringe

℞ Only

Recommended Dosage: See prescribing information.

ATTENTION PHARMACIST:
Each patient is required to receive the enclosed Medication Guide.

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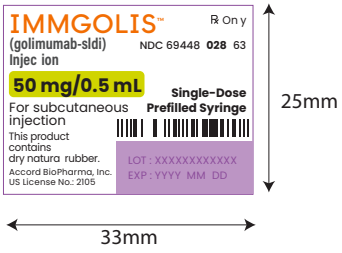
Reference ID: 5799301


IMMGOLIS™
℞ Only
(golimumab-sldi)
Injection
NDC 69448 028 63
50 mg/0.5 mL
Single-Dose
Prefilled Syringe
For subcutaneous injection
This product contains dry natural rubber.
Accord BioPharma, Inc.
US License No.: 2105
LOT : XXXXXXXXXXX
EXP : YYYY MM DD
25mm
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(b) (4)

IMMGOLIS INTRI™
(golimumab-sldi) injec ion

50 mg/4 mL (12.5 mg/mL)

Recommended Dosage:
See Prescribing Information.

Store refrigerated at 36°F to 46°F (2°C to 8°C). Store in original carton to protect from light. Do not freeze. Do not shake.

IMMGOLIS INTRI may be stored at room temperature up to 77°F (25°C) for a maximum single period of 15 days in the original carton to protect from light. Do not return it to the refrigerator. Discard if not used within 15 days at room temperature. Discard after _____/ _____/ _____.

NDC 69448-**029**-64 ℞ Only

IMMGOLIS INTRI™
(golimumab-sldi) injec ion

50 mg/4 mL (12.5 mg/mL)

For intravenous infusion

4 mL Single-dose vial.

Discard unused portion.
ATTENTION PHARMACIST: Each patient is required to receive the enclosed Medication Guide.

accord™

IMMGOLIS INTRI™
(golimumab-sldi) injec ion

50 mg/4 mL (12.5 mg/mL)

For intravenous infusion

4 mL Single-dose vial.

Discard unused portion.
Each 4-mL vial of IMMGOLIS INTRI contains 50 mg golimumab-sldi, histidine (1.60 mg), L-histidine monohydrochloride monohydrate (6.20 mg), polysorbate 80 (0.80 mg), trehalose (307.62 mg), and water for injection.

Keep out of reach of children.

No preservative.

accord™

NDC 69448-**029**-64 ℞ Only

Manufactured at:
Bio-Thera Solutions, Ltd.
155 Yaotianhe Street, Huangpu District, Guangzhou,
Guangdong Province, China, 511356

Manufactured by:
Accord BioPharma, Inc.
8041 Arco Corporate Dr., Suite 200
Raleigh, NC 27617 USA
U.S. License No: 2105

3 69448 02964 7

FPO

accord™

For intravenous infusion

50 mg/4 mL (12.5 mg/mL)

(golimumab-sldi) injec ion

IMMGOLIS INTRI™

NDC 69448-**029**-64 ℞ Only

FPO

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Representation of batch prompts and data printed black online

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S/N : XXXXXXXXXX
LOT : XXXXXXXXXX
EXP : YYYY-MM-DD

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Lot(XXXXXXXXXX)
EXP(YYYY-MM-DD)

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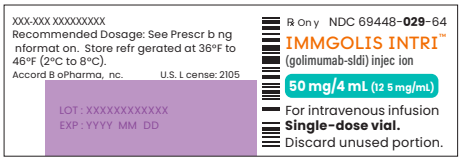
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Recommended Dosage: See Prescr b ng nformat on. Store refr gerated at 36°F to 46°F (2°C to 8°C).
Accord B oPharma, nc. U.S. L cense: 2105
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℞ Only NDC 69448-029-64
IMMGOLIS INTRI™
(golimumab-sldi) injec ion
50 mg/4 mL (12 5 mg/mL)
For intravenous infusion
Single-dose vial.
Discard unused portion.

(b) (4)

152 mm

63 mm

LOT : XXXXXXXXXXX
EXP : YYYY-MM-DD

IMMGOLIS™

(golimumab-sldi)
Injec ion

100 mg/mL

For Subcutaneous injection.

Accord BioPharma, Inc.
8041 Arco Corporate Drive, Suite 200
Raleigh, NC 27617 USA U.S. License No.: 2105

accord™

NDC 69448-**029**-63
℞ Only

1 mL single-dose prefilled syringe

Store refrigerated at 36°F to 46°F (2°C to 8°C)
to protect from light.
Do not shake. Do not freeze.

Recommended Dosage:
See prescribing information.

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(b) (4)

Representation of batch prompts and data printed black online

2D

GTIN : XXXXXXXXXXXXX
S/N : XXXXXXXXXX
LOT : XXXXXXXXXX
EXP : YYYY-MM-DD

2D Code to incorporate:
GTIN(XXXXXXXXXXXXX)
S/N(XXXXXXXXXX)
Lot(XXXXXXXXXX)
EXP(YYYY-MM-DD)

FPO

R Only

NDC 69448-**029**-63

IMMGOLIS™
(golimumab-sldi)
Injec ion

100 mg/mL

1 mL single-dose prefilled syringe

FOR SUBCUTANEOUS INJECTION

Sterile solution in a single-dose prefilled syringe.
No preservative.
Discard unused portion.
Recommended Dosage: See prescribing information.

This product contains dry natural rubber.

accord™

FPO

IMMGOLIS™
(golimumab-sldi)
Injec ion

100 mg/mL

1 mL single-dose prefilled syringe

FOR SUBCUTANEOUS INJECTION

Manufactured at:
Bio-Thera Solutions, Ltd.
155 Yaotianhe Street,
Huangpu District, Guangzhou,
Guangdong, China, 511356

Manufactured by:
Accord BioPharma, Inc.
8041 Arco Corporate Dr., Suite 200
Raleigh, NC 27617 USA
U.S. License No: 2105

(b) (4)

IMMGOLIS™
(golimumab-sldi)
Injec ion

100 mg/mL

1 mL single-dose prefilled syringe

℞ Only

NDC 69448-**029**-63

IMMGOLIS™
(golimumab-sldi)
Injec ion

100 mg/mL

1 mL single-dose prefilled syringe

FOR SUBCUTANEOUS INJECTION

accord™

Sterile solution in single-dose prefilled syringe. No preservative. Store refrigerated at 36°F to 46°F (2°C to 8°C) and keep in carton to protect from light. Do not shake. Do not freeze.
IMMGOLIS may be stored at room temperature up to 77°F (25°C) for a maximum single period of 15 days in the original carton to protect from light. Do not return it to the refrigerator. Discard if not used within 15 days at room temperature. Write date removed from the refrigerator __/__/____.
Keep out of reach of children.

Each 1 mL single-dose prefilled syringe contains:
100 mg golimumab-sldi, histidine (0.28 mg), L-histidine monohydrochloride monohydrate (1.72 mg), polysorbate 80 (0.20 mg), trehalose (76.905 mg), and water for injection.

Recommended Dosage: See prescribing Information.

3 69448 02963 0

℞ Only

IMMGOLIS™
(golimumab-sldi)
Injec ion

100 mg/mL

1 mL single-dose prefilled syringe

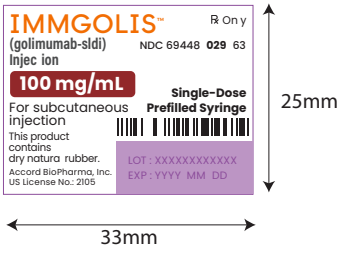
℞ Only

Recommended Dosage: See prescribing information.

ATTENTION PHARMACIST:
Each patient is required to receive the enclosed Medication Guide.

(b) (4)

Reference ID: 5799301


IMMGOLIS™
℞ Only
(golimumab-sldi)
Injection
NDC 69448 029 63
100 mg/mL
Single-Dose
Prefilled Syringe
For subcutaneous
injection
This product
contains
dry natural rubber.
Accord BioPharma, Inc.
US License No.: 2105
LOT : XXXXXXXXXXX
EXP : YYYY MM DD
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33mm

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

RAJ NAIR
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