Hulio360™

Support designed around your patients

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with adalimumab products including HULIO® (adalimumab-fkjp) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue HULIO if a patient develops a serious infection or sepsis.

Reported infections include:

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

Please see additional Important Safety Information and Indications on pages 8-11, and accompanying Full Prescribing Information, including BOXED WARNING for HULIO.

Hulio®
(adalimumab-fkjp) injection

Simple from the start

HULIO360™ and its team of Patient Onboarding Specialists help with onboarding and provide a range of resources to support your patients from the moment they're enrolled.

Enrollment made easy

The good news is, your patient can be enrolled in HULIO360 automatically as long as you prescribe Hulio / adalimumab-fkjp in one of the following ways:

1-866-335-7539

Fax your completed HULIO360 Enrollment and Prescription Form

Scan the QR code to download the form, or visit **HulioHCP.com**

OR

e-Prescribe

Submit your prescription and select The Lash Group* for the pharmacy

(Be sure to include your patient's mobile number)†

*The Lash Group, 1800 Innovation Pt, Fort Mill, SC 29715; NCPDP: 4237942.

†By providing the patient's phone number, you represent that your patient is aware of the disclosure and has given consent to be contacted regarding this prescription, and by the fulfillment pharmacy.

Hulio® (adalimumab-fkjp) injection

HULIO360™ has your patient's back through every step of their treatment experience

1

Helping your patient access Hulio

While your patient's enrollment is being processed, we:

- Initiate benefits verification and prior authorization support
- Provide information on financial options and copay assistance*
- Assess Bridge Program eligibility to avoid treatment delays during initial benefit approval†

Once enrolled, your patient will receive a welcome call from a Patient Onboarding Specialist. Have them add **1-833-444-8546** to their contacts so they don't miss it.

2

Getting your patient started on Hulio

Following the initial welcome call, your patient will receive:

- A welcome kit with important information about managing their condition with HULIO
- A call to schedule their in-home visit with an In-home Injection Training Nurse or virtual training from a Pharmacist Educator‡

Sharps containers for disposing used injection devices are available upon request.

3

Helping your patient stay on Hulio

Throughout their treatment experience, patients can receive:

- A refrigerated travel bag upon enrollment
- Text message injection reminders‡
- Ongoing support from Pharmacist Educators‡

*Eligibility restrictions apply. Not valid for uninsured patients or patients who are covered by a state- or federal-funded healthcare program. For full terms and conditions, visit www.hulio.com/copay.

†Eligibility restrictions apply. For Bridge Program terms and conditions, please visit www.huliohcp.com/bridgeprogramtermsandconditions.

‡Available for patients who opt in.

Hulio®
(adalimumab-fkjp) injection

Hulio360™

Support designed around your patients

HULIO360™ Patient Support Services is available
Monday through Friday, 8 AM to 8 PM ET
at **1-833-44-HULIO (1-833-444-8546)**

Hulio®
(adalimumab-fkjp) injection

Hulio®
(adalimumab-fkjp) injection

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with adalimumab products including HULIO® (adalimumab-fkjp) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue HULIO if a patient develops a serious infection or sepsis.

Reported infections include:

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

Carefully consider the risks and benefits of treatment with HULIO prior to initiating therapy in patients:

1) with chronic or recurrent infection, 2) who have been exposed to TB, 3) with a history of opportunistic infection, 4) who resided in or traveled in regions where mycoses are endemic, 5) with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HULIO, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start HULIO during an active infection, including localized infections.
- Patients older than 65 years, patients with comorbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully, and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of HULIO with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of HULIO treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials of some TNF blockers, including adalimumab products, more cases of malignancies were observed among TNF-blocker-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy, for the presence of NMSC prior to and during treatment with HULIO.
- In adalimumab clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general US population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.
- Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSENSITIVITY

- Anaphylaxis and angioneurotic edema have been reported following administration of adalimumab products. If a serious allergic reaction occurs, stop HULIO and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including HULIO, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.

Hulio®
(adalimumab-fkjp) injection

IMPORTANT SAFETY INFORMATION (continued)

- Exercise caution in patients who are carriers of HBV and monitor them during and after HULIO treatment.
- Discontinue HULIO and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming HULIO after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including adalimumab products, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome.
- Exercise caution when considering HULIO for patients with these disorders; discontinuation of HULIO should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with adalimumab products.
- Consider stopping HULIO if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Cases of worsening CHF have been observed with adalimumab products; exercise caution and monitor carefully.

AUTOIMMUNITY

- Treatment with adalimumab products may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on HULIO should not receive live vaccines
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating HULIO therapy.
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to HULIO in utero is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE REACTIONS

- The most common adverse reactions in adalimumab clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

INDICATIONS:

- **Rheumatoid Arthritis:** HULIO is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. HULIO can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).
- **Juvenile Idiopathic Arthritis:** HULIO is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. HULIO can be used alone or in combination with methotrexate.
- **Psoriatic Arthritis:** HULIO is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. HULIO can be used alone or in combination with non-biologic DMARDs.
- **Ankylosing Spondylitis:** HULIO is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- **Crohn's Disease:** HULIO is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis:** HULIO is indicated for the treatment of moderately to severely active ulcerative colitis in adult patients.
  Limitations of Use:
  The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque Psoriasis:** HULIO is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HULIO should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis Suppurativa:** HULIO is indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.
- **Uveitis:** HULIO is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

Please see accompanying Full Prescribing Information including BOXED WARNING.

Scan the QR code to learn more about
all the services available to your patients,
or visit **HulioHCP.com/Hulio360**

HUL-2023-00055-US