

HUMIRA Uses¹

HUMIRA is a prescription medicine used:

- **To reduce the signs and symptoms of:**
 - **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA)** in children 2 years of age and older. HUMIRA can be used alone, with methotrexate, or with certain other medicines.
 - **Moderate to severe Crohn's disease (CD)** and to achieve and maintain clinical remission in children 6 years of age and older when certain other treatments have not worked well enough.
 - **Moderate to severe hidradenitis suppurativa (HS)** in people 12 years and older.
- **To treat non-infectious intermediate** (middle part of the eye), **posterior** (back of the eye), and **panuveitis** (all parts of the eye) **in adults and children 2 years of age and older.**

Important Safety Information About HUMIRA® (adalimumab)¹

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

You should discuss the potential benefits and risks of HUMIRA with your doctor. HUMIRA is a TNF blocker medicine that can lower the ability of your immune system to fight infections. You should not start taking HUMIRA if you have any kind of infection unless your doctor says it is okay.

- **Serious infections have happened in people taking HUMIRA. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections.** Your doctor should test you for TB before starting HUMIRA, and check you closely for signs and symptoms of TB during treatment with HUMIRA, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.
- **Cancer.** For children and adults taking TNF blockers, including HUMIRA, the chance of getting lymphoma or other cancers may increase. There have been cases of unusual cancers in children, teenagers, and young adults using TNF blockers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. If using TNF blockers including HUMIRA, your chance of getting two types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life-threatening if treated; tell your doctor if you have a bump or open sore that doesn't heal.

What should I tell my doctor BEFORE starting HUMIRA?

Tell your doctor about all of your health conditions, including if you:

- Have an infection, are being treated for infection, or have symptoms of an infection
- Get a lot of infections or infections that keep coming back
- Have diabetes
- Have TB or have been in close contact with someone with TB, or were born in, lived in, or traveled where there is more risk for getting TB
- Live or have lived in an area (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections, such as histoplasmosis, coccidioidomycosis, or blastomycosis. These infections may happen or become more severe if you use HUMIRA. Ask your doctor if you are unsure if you have lived in these areas
- Have or have had hepatitis B
- Are scheduled for major surgery
- Have or have had cancer
- Have numbness or tingling or a nervous system disease such as multiple sclerosis or Guillain-Barré syndrome
- Have or had heart failure
- Have recently received or are scheduled to receive a vaccine. HUMIRA patients may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting HUMIRA

- Are allergic to rubber, latex, or any HUMIRA ingredients
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed
- Have a baby and you were using HUMIRA during your pregnancy. Tell your baby's doctor before your baby receives any vaccines

Also tell your doctor about all the medicines you take. You should not take HUMIRA with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

What should I watch for AFTER starting HUMIRA?

HUMIRA can cause serious side effects, including:

- **Serious infections.** These include TB and infections caused by viruses, fungi, or bacteria. Symptoms related to TB include a cough, low-grade fever, weight loss, or loss of body fat and muscle.
- **Hepatitis B infection in carriers of the virus.** Symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.
- **Allergic reactions.** Symptoms of a serious allergic reaction include hives, trouble breathing, and swelling of your face, eyes, lips, or mouth.
- **Nervous system problems.** Signs and symptoms include numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems** (decreased blood cells that help fight infections or stop bleeding). Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **Heart failure** (new or worsening). Symptoms include shortness of breath, swelling of your ankles or feet, and sudden weight gain.
- **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or rash on your cheeks or arms that gets worse in the sun.
- **Liver problems.** Symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of your stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis** (new or worsening). Symptoms include red scaly patches or raised bumps that are filled with pus.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Common side effects of HUMIRA include injection site reactions (pain, redness, rash, swelling, itching, or bruising), **upper respiratory infections** (sinus infections), **headaches, rash, and nausea.** These are not all of the possible side effects with HUMIRA. Tell your doctor if you have any side effect that bothers you or that does not go away.

Remember, tell your doctor right away if you have an infection or symptoms of an infection, including:

- Fever, sweats, 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
- Urinating more often than normal
- Feeling very tired

HUMIRA is given by injection under the skin.

This is the most important information to know about HUMIRA. For more information, talk to your health care provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.

Reference: 1. HUMIRA Injection [package insert]. North Chicago, IL: AbbVie Inc.

Please see full Prescribing Information, including Medication Guide or visit www.rxabbvie.com/pdf/humira.pdf and discuss with your child's doctor.

Enrollment Form

Instructions:
 Fax to HUMIRA Complete (1.866.980.1066)
 Questions? Call 1.800.4HUMIRA (1.800.448.6472)

Required fields are marked with an asterisk (*).

1 Patient's Information - To be completed by the child's parent or authorized caregiver. Please print clearly.

First Name*: _____ Last Name*: _____ Date of Birth: ____ / ____ / ____ Gender: (check one) M F
 Name of Patient's Parent or authorized caregiver*: _____ Relationship to Patient: _____
 Address*: _____ City*: _____ State*: _____ ZIP*: _____
 Home Phone*: _____ Parent/Caregiver Mobile Phone: _____ Parent/Caregiver Email*: _____ Spanish interpreter needed

I consent to receive recurring text messages from AbbVie, including service updates, medication reminders and marketing messages, to the above mobile number. Message and data rates may apply. My consent is not a condition of receiving goods or services. I can reply HELP for help. I can text STOP to unsubscribe any time.

Best Time to Call: Monday-Friday Anytime Morning Afternoon Evening

When did the patient start on treatment? Not Yet Started 0-3 Months Ago 4-6 Months Ago 7-12 Months Ago Over 12 Months Ago

For which condition is the patient being treated? (This product support program is for approved HUMIRA indications only.)

Moderate to Severe Polyarticular Juvenile Idiopathic Arthritis (JIA) NI Uveitis pediatric patient† Moderate to Severe Pediatric Crohn's Disease Hidradenitis Suppurativa adolescent patient

†Non-infectious intermediate, posterior, and panuveitis.

By enrolling, I represent that I am the patient's authorized caregiver. As part of HUMIRA Complete you and the patient may receive your own Nurse Ambassador provided by AbbVie. Ambassadors do not work under the direction of your health care professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals. To learn about AbbVie's privacy practices and your privacy choices, visit www.abbvie.com/privacy.html.

I would like to receive news and updates about AbbVie's products, clinical trials, research opportunities, programs, and other information that may be of interest to me.

▼ For Health Care Provider Use ▼

2 Prescriber Information - To be completed by prescriber. Please print clearly.

Name*: _____ NPI #: _____
 Address: _____ City: _____ State: _____ ZIP*: _____
 Office Contact Name: _____ Phone: _____ Fax*: _____

3 Nurse Injection Training Request - To be completed by prescriber.

Dosing is the same for Pen and prefilled syringe, given as SC injection. (This is not a prescription.)

Please check the appropriate dosing regimen the patient has been prescribed. The RN will use this information for training purposes.

Dosing for JIA based on patient weight:	If 10 kg (22 lbs) to <15 kg (33 lbs)	<input type="checkbox"/> 10 mg QOW	
	If 15 kg (33 lbs) to <30 kg (66 lbs)	<input type="checkbox"/> 20 mg QOW	
	If ≥30 kg (66 lbs)	<input type="checkbox"/> 40 mg QOW	
	Other HUMIRA Dose	<input type="checkbox"/> Other:	
Dosing for Pediatric Uveitis[‡] based on patient weight: <small>‡Non-infectious intermediate, posterior, and panuveitis.</small>	If 17 kg (37 lbs) to <40 kg (88 lbs)	<input type="checkbox"/> 80 mg Day 1; 40 mg Day 15; 20 mg QOW thereafter	
	If ≥40 kg (88 lbs)	<input type="checkbox"/> 160 mg Day 1; 80 mg Day 15; 40 mg QOW thereafter OR <input type="checkbox"/> 80 mg Day 1; 80 mg Day 2; 80 mg Day 15; 40 mg QOW thereafter	
	Other HUMIRA Dose	<input type="checkbox"/> Other:	
	Dosing for Pediatric Crohn's Disease based on patient weight:	If 30 kg (66 lbs) to <60 kg (132 lbs)	<input type="checkbox"/> 80 mg Day 1; 40 mg Day 8 and QOW thereafter
If ≥60 kg (132 lbs)		<input type="checkbox"/> 160 mg Day 1; 80 mg Day 15; 40 mg Day 29 and QW thereafter OR <input type="checkbox"/> 80 mg Day 1; 80 mg Day 2; 80 mg Day 15; 40 mg Day 29 and QW thereafter	
		<input type="checkbox"/> 160 mg Day 1; 80 mg Day 15; 80 mg Day 29 and QOW thereafter OR <input type="checkbox"/> 80 mg Day 1; 80 mg Day 2; 80 mg Day 15; 80 mg Day 29 and QOW thereafter	
		Other HUMIRA Dose	<input type="checkbox"/> Other:

Nursing Orders: My signature on this Enrollment Form indicates I am requesting a Registered Nurse to either (i) provide patient training on proper technique for self-administration of HUMIRA or, if needed, (ii) the administration of HUMIRA during the teaching visit. Order valid for up to one year.

Prescriber's Signature*

Date*

Important Information:

By submitting this form you are referring the above patient to AbbVie's patient support program to determine eligibility and receive support related to an AbbVie product. AbbVie, its affiliates, collaborators and agents will use the information collected about you and your patient to provide the patient support and perform research and analytics, on a de-identified basis, for management of the program. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit www.abbvie.com/privacy.html. Please share this information with your patient.

INDICATIONS¹

- **Juvenile Idiopathic Arthritis:** HUMIRA is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- **Pediatric Crohn's Disease:** HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.
- **Hidradenitis Suppurativa:** HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.
- **Uveitis:** HUMIRA is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION¹

SERIOUS INFECTIONS

Patients treated with HUMIRA 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 HUMIRA 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 HUMIRA use and during therapy. Initiate treatment for latent TB prior to HUMIRA 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 HUMIRA 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 HUMIRA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.**

- Do not start HUMIRA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid 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 HUMIRA 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 HUMIRA. 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 HUMIRA. 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 of these patients had received treatment with azathioprine or 6-mercaptopurine 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 HUMIRA treatment prior to initiating or continuing therapy in a patient with known malignancy.

- In clinical trials, more cases of malignancies were observed among HUMIRA-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for HUMIRA-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 HUMIRA.
- In HUMIRA clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. 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 HUMIRA administration. If a serious allergic reaction occurs, stop HUMIRA and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including HUMIRA, 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.
- Exercise caution in patients who are carriers of HBV and monitor them during and after HUMIRA treatment.
- Discontinue HUMIRA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming HUMIRA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including HUMIRA, 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 HUMIRA for patients with these disorders; discontinuation of HUMIRA 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 HUMIRA.
- Consider stopping HUMIRA if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

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

AUTOIMMUNITY

- Treatment with HUMIRA 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 HUMIRA should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating HUMIRA 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 HUMIRA *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 HUMIRA clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

Reference: 1. HUMIRA Injection [package insert]. North Chicago, IL: AbbVie Inc.

Please see full [Prescribing Information](#).