

# Make Sure Your Patients Start on the Appropriate HUMIRA Dose

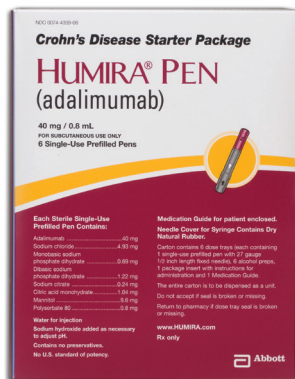
- HUMIRA has **6** indications
- **Different** indications have **different** approved starting doses
- Call the prescribing physician if you have any questions or concerns about the starting dose prescribed

1

**Crohn's Disease (CD):** HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. HUMIRA is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.<sup>1</sup>

## INITIATION: Crohn's Disease Starter Package

### ▶ Starting Dose for New Patient



**NDC# 0074-4339-06**  
Six (6) 40 mg Pens

**160 mg then 80 mg**  
Day 1\* – Initial treatment  
Inject four (4) Pens (160 mg) SC  
Day 15 – 2 weeks later  
Inject two (2) Pens (80 mg) SC

\* First dose can be administered as 4 injections on 1 day or 2 injections per day for 2 consecutive days.<sup>1</sup>

## MAINTENANCE: HUMIRA Pen Carton



**NDC# 0074-4339-02**  
Two (2) 40 mg Pens

**40 mg**  
Day 29 and eow thereafter  
Inject one (1) Pen (40 mg) SC  
eow = every other week

## Safety Considerations<sup>1</sup>

Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. These infections include active tuberculosis (TB), reactivation of latent TB, invasive fungal infections, and bacterial, viral, and other infections due to opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Patients treated with HUMIRA also may be at risk for other serious adverse reactions including malignancies, anaphylaxis, hepatitis B virus reactivation, demyelinating disease, cytopenias, pancytopenia, heart failure, and a lupus-like syndrome.

HUMIRA must be refrigerated at 2 to 8° C (36 to 46° F).<sup>1</sup>

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Please see Important Safety Information, including **BOXED WARNING** on Serious Infections and Malignancy, on last page.

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2

**Plaque Psoriasis (Ps): HUMIRA** 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. HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.<sup>1</sup>

## INITIATION: Psoriasis Starter Package

### ▶ Starting Dose for New Patient



**NDC# 0074-4339-07**  
Four (4) 40 mg Pens

**80 mg then 40 mg**

**Day 1 – Initial treatment**  
Inject two (2) Pens (80 mg) SC

**Day 8 – 1 week later**  
Inject one (1) Pen (40 mg) SC

**Day 22 – 2 weeks later**  
Inject one (1) Pen (40 mg) SC

## MAINTENANCE: HUMIRA Pen Carton



**NDC# 0074-4339-02**  
Two (2) 40 mg Pens

**40 mg**

**Day 36 and eow thereafter**  
Inject one (1) Pen (40 mg) SC

eow = every other week

3

**Juvenile Idiopathic Arthritis (JIA): HUMIRA** is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older.<sup>1</sup>

## INITIATION & MAINTENANCE: Dosing by weight of patient\*

### Pediatric Prefilled Syringe Carton



**NDC# 0074-9374-02**  
Two (2) 20 mg  
prefilled syringes

**20 mg**

**For patients 15 kg (33 lbs)  
to <30 kg (66 lbs)**  
Inject one (1) (20 mg)  
prefilled syringe eow

eow = every other week

### Prefilled Syringe Carton



**NDC# 0074-3799-02**  
Two (2) 40 mg  
prefilled syringes

**40 mg**

**For patients ≥30 kg (66 lbs)**  
Inject one (1) (40 mg)  
prefilled syringe eow

eow = every other week

### HUMIRA Pen Carton



**NDC# 0074-4339-02**  
Two (2) 40 mg  
Pens

**40 mg**

**For patients ≥30 kg (66 lbs)**  
Inject one (1) (40 mg)  
Pen eow

eow = every other week

\* Doses may be administered with either the HUMIRA Pen or the HUMIRA prefilled syringe in patients ≥30 kg (66 lbs).

## Administration Considerations<sup>1</sup>

- Anaphylaxis or serious allergic reactions may occur
- In placebo-controlled trials, 20% of HUMIRA-treated patients developed injection site reactions compared with 14% of patients receiving placebo. Most reactions were mild and generally did not necessitate discontinuation
- A patient may self-inject HUMIRA if a physician determines that it is appropriate and with medical follow-up, as necessary, after proper training in subcutaneous injection technique

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**4 Rheumatoid Arthritis (RA): HUMIRA** 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.<sup>1</sup>

**5 Psoriatic Arthritis (PsA): HUMIRA** is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis.<sup>1</sup>

**6 Ankylosing Spondylitis (AS): HUMIRA** is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.<sup>1</sup>

### INITIATION & MAINTENANCE: HUMIRA Pen *or* Prefilled Syringe Carton<sup>†</sup>

#### HUMIRA Pen Carton



**NDC# 0074-4339-02**  
Two (2) 40 mg Pens

**40 mg**  
Inject one (1) (40 mg) Pen eow

eow = every other week

#### Prefilled Syringe Carton



**NDC# 0074-3799-02**  
Two (2) 40 mg prefilled syringes

**40 mg**  
Inject one (1) (40 mg) prefilled syringe eow

eow = every other week

<sup>†</sup> Doses may be administered with either the HUMIRA Pen or the HUMIRA prefilled syringe. Some moderate to severe RA patients not taking methotrexate may benefit from 40 mg SC every week.

### Safety Considerations<sup>1</sup>

Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. These infections include active tuberculosis (TB), reactivation of latent TB, invasive fungal infections, and bacterial, viral, and other infections due to opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which HUMIRA is a member. Patients treated with HUMIRA also may be at risk for other serious adverse reactions including malignancies, anaphylaxis, hepatitis B virus reactivation, demyelinating disease, cytopenias, pancytopenia, heart failure, and a lupus-like syndrome.

HUMIRA must be refrigerated at 2 to 8° C (36 to 46° F).<sup>1</sup>

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## IMPORTANT SAFETY INFORMATION<sup>1</sup>

### WARNINGS

#### 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. HUMIRA should be discontinued 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. Patients should be tested for latent TB before HUMIRA use and during therapy. Treatment for latent infection should be initiated 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. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral and other infections due to opportunistic pathogens.**

**The risks and benefits of treatment with HUMIRA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored 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.**

#### MALIGNANCY

**Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which HUMIRA is a member.**

#### Serious Infections

Do not start HUMIRA in patients with an active infection, including localized infections. Exercise caution in patients with chronic or recurrent infection or with underlying conditions which may predispose them to infection, patients who have been exposed to TB, or patients who have resided or traveled in regions where TB or mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, are endemic. Treatment of latent TB infection prior to therapy with TNF-blocking agents has been shown to reduce the risk of TB reactivation during therapy. When TB skin testing is performed, an induration size of 5 mm or greater should be considered positive, even if vaccinated previously with Bacille Calmette-Guerin (BCG). HUMIRA should be discontinued if a patient develops a serious infection or sepsis. Patients who develop a new infection should undergo a prompt and complete diagnostic workup, and appropriate antimicrobial therapy should be initiated.

#### Malignancies

More cases of malignancies were observed among patients receiving TNF blockers, including HUMIRA, compared to control patients in clinical trials. These malignancies, other than lymphoma and non-melanoma skin cancer, were similar in type and number to what would be expected in the general population. In the controlled and open-label portions of HUMIRA clinical trials, there was an approximately 3-fold higher rate of lymphoma than expected in the general population. Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use.

Postmarketing cases of malignancies, some fatal, were reported among children, adolescents, and young adults receiving TNF blockers, of which HUMIRA is a member. Approximately half of these were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents. The malignancies occurred after a median of 30 months of therapy (range 1 to 84 months). Most patients were receiving concomitant immunosuppressants.

The potential role of TNF-blocking therapy in the development of malignancies is not known.

#### Hypersensitivity

Anaphylaxis and angioneurotic edema have been reported rarely following HUMIRA administration.

#### Hepatitis B 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. Patients at risk for HBV infection should be evaluated for prior evidence of HBV infection before initiating TNF blocker therapy. For patients identified as carriers of HBV, exercise caution when prescribing HUMIRA, with careful evaluation and monitoring prior to and during treatment. HUMIRA should be stopped and antiviral therapy should be initiated in patients who develop hepatitis B reactivation.

#### Neurologic Reactions

TNF-blocking agents, including HUMIRA, have been associated with rare cases of new onset or exacerbation of central nervous system demyelinating disease, including multiple sclerosis, and peripheral demyelinating disease, including Guillain-Barré syndrome. Exercise caution when considering HUMIRA for patients with preexisting or recent-onset central or peripheral nervous system demyelinating disorders.

#### Hematologic Reactions

Rare reports of pancytopenia including aplastic anemia have been reported with TNF-blocking agents. Medically significant cytopenia (e.g. thrombocytopenia, leukopenia) has been infrequently reported with HUMIRA. The causal relationship of these reports to HUMIRA remains unclear.

#### Congestive Heart Failure

Worsening congestive heart failure (CHF) has been observed with TNF-blocking agents, including HUMIRA, and new-onset CHF has been reported with TNF-blocking agents.

#### 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. It is recommended that juvenile idiopathic arthritis patients, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating HUMIRA therapy.

#### Drug Interactions

Serious infections were seen in studies with concurrent use of anakinra and another TNF-blocking agent; therefore, the combination of HUMIRA and anakinra is not recommended.

#### Adverse Reactions

In the placebo-controlled clinical studies of adult patients with rheumatoid arthritis, the most frequent adverse reactions vs placebo were injection site reactions (20% vs 14%), upper respiratory infection (17% vs 13%), injection site pain (12% vs 12%), headache (12% vs 8%), rash (12% vs 6%), and sinusitis (11% vs 9%). Discontinuations due to adverse events were 7% for HUMIRA vs 4% for placebo.

In HUMIRA clinical trials for ankylosing spondylitis, psoriatic arthritis, Crohn's disease, and plaque psoriasis, the safety profile for patients treated with HUMIRA was similar to the safety profile seen in patients with rheumatoid arthritis. In the placebo-controlled clinical trials in plaque psoriasis, the incidence of arthralgia was 3% in HUMIRA-treated patients versus 1% in controls.

In general, the adverse reactions in juvenile idiopathic arthritis (JIA) patients were similar in frequency and type to those seen in adult patients. Severe adverse reactions reported in the clinical trial in JIA included neutropenia, streptococcal pharyngitis, increased aminotransferases, herpes zoster, myositis, metrorrhagia, and appendicitis. Serious infections were observed in 4% of patients within approximately 2 years of initiation of treatment with HUMIRA and included cases of herpes simplex, pneumonia, urinary tract infection, pharyngitis, and herpes zoster. The safety of HUMIRA in pediatric patients for uses other than JIA has not been established.

**Reference: 1.** HUMIRA Injection [package insert]. North Chicago, IL: Abbott Laboratories.

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