# Humira

(adalimumab)

**NEW INDICATION**

Drug Update
Slideshow

MPR

# Introduction

- **Brand name:** Humira
- **Generic name:** Adalimumab
- **Pharmacological class:** Tumor necrosis factor (TNF) blocker
- **Strength and Formulation:** 10mg/0.2mL, 20mg/0.4mL, 40mg/0.4mL, 40mg/0.8mL; soln for SC inj; preservative-free
- **Manufacturer:** AbbVie
- **How supplied:** Single-dose prefilled syringe—2; Single-dose prefilled pen (40mg)—2, 4 (Starter Package)
- **Legal Classification:** Rx

# HUMIRA


2 SINGLE-USE PREFILLED PENS
HUMIRA® PEN
adalimumab
40 mg / 0.8 mL
FOR SUBCUTANEOUS USE ONLY
ATTENTION PHARMACIST: Each patient is required to receive the enclosed Medication Guide.
Needle Cover for Syringe Contains Dry Natural Rubber.
The entire carton is to be dispensed as a unit.
Return to pharmacy if dose tray seal is broken or missing.
▼ To Open
This carton contains:
• 2 dose trays (each containing 1 single-use prefilled pen with 27 gauge 1/2 inch length fixed needle)
• 2 alcohol preps
• 1 Medication Guide
• 1 package insert
• 1 Instructions for Use
Rx only
www.HUMIRA.com
abbvie
HUMIRA® PEN
(adalimumab)

# New Indication

- **Non-infectious intermediate, posterior and panuveitis**

- Also indicated for:
  - Moderately-to-severely active rheumatoid arthritis
  - Moderately-to-severely active polyarticular juvenile idiopathic arthritis
  - Active psoriatic arthritis
  - Active ankylosing spondylitis
  - Moderately-to-severely active Crohn’s disease
  - Moderately-to-severely active ulcerative colitis
  - Moderate-to-severe hidradenitis suppurativa
  - Moderate-to-severe chronic plaque psoriasis

# Dosage & Administration

- **Uveitis**
  - Inject SC into thigh or abdomen; rotate inj sites; supervise 1st dose
  - ≥18yrs: initially 80mg, followed by 40mg every other week starting one week after initial dose

- *For other indications, see full labeling*

# Considerations for Special Populations

- **Pregnancy:** Actively crosses placenta during 3rd trimester; may affect immune response in *in utero* exposed infants
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** <18yrs: not established
- **Geriatric:** Use caution (higher incidence of infections and malignancies)

# Warnings/Precautions

- Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, viral, invasive fungal [treat empirically if develops], or other pathogens)
- Active infections: do not initiate therapy
- Chronic or history of recurring infections
- Conditions that predispose to infection
- Travel to, or residence in, areas with endemic TB or mycoses

# Warnings/Precautions

- Test/treat latent TB and HBV infection prior to initiating therapy
- Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops
- Lymphoma and other malignancies
- CHF (monitor)
- Immunosuppression

# Warnings/Precautions

- Discontinue if lupus-like syndrome with antibody formation or serious hypersensitivity reaction occurs
- Central or peripheral nervous system demyelinating disorders; consider discontinuing if develops
- Pediatric patients: follow up on current immunizations before starting therapy; consider risks/benefits prior to vaccinating exposed infants *in utero*
- Latex allergy
- Elderly

# Interactions

- **Avoid** live vaccines
- Concomitant other biologic DMARDs (eg, abatacept or anakinra) or other TNF blockers: not recommended
- Immunosuppressants increase risk of infection
- Concomitant CYP450 substrates with narrow therapeutic index (eg, warfarin, cyclosporine, theophylline); monitor and adjust dose of these drugs

# Adverse Reactions

- Inj site reactions
- Infections (may be serious)
- Headache
- Nausea
- Rash
- Abdominal pain
- Malignancies (eg, lymphoma: especially children)
- Blood dyscrasias
- Neurological events
- Antibody formation
- Lupus-like syndrome

# Mechanism of Action

- Adalimumab binds specifically to TNF-alpha and blocks its interaction with the p55 and p75 cell surface TNF receptors
- Adalimumab also lyses surface TNF expressing cells *in vitro* in the presence of a complement
- Adalimumab modulates biological responses that are induced or regulated by TNF, including changes in the levels of adhesion molecules responsible for leukocyte migration

# Clinical Trials

- The safety and efficacy of Humira were assessed in adults with non-infectious intermediate, posterior and panuveitis in 2 randomized, double-masked, placebo-controlled studies **(UV I and II)**

- Patients received placebo or Humira 80mg initially followed by 40mg every other week starting 1 week after the initial dose

# Clinical Trials

- The primary efficacy endpoint in both studies was **time to treatment failure**, defined as:
  - Development of new inflammatory chorioretinal and/or inflammatory retinal vascular lesions
  - Increase in anterior chamber (AC) cell grade or vitreous haze (VH)
  - Decrease in best corrected visual acuity (BCVA)

# Clinical Trials

- **UV I** (n=217) evaluated patients with active uveitis while being treated with corticosteroids
- **UV II** (n=226) evaluated patients with inactive uveitis while being treated with corticosteroids
- Both studies demonstrated statistically significant reduction of risk of treatment failure in the Humira-treated group vs. placebo

# Clinical Trials

- **UV I**
  - Treatment failure was seen **78.5%** of the placebo group vs. **54.5%** of Humira group (HR 0.50, 95% CI: 0.36, 0.70)
- **UV II**
  - Treatment failure was seen in **55.0%** of the placebo group vs. **39.1%** of the Humira group (HR 0.57, 95% CI: 0.39, 0.84)

- For more clinical data, see full labeling

# Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/humira/drug/778/