# ACR/ARP Medication Guide



#### ASSOCIATION of RHEUMATOLOGY PROFESSIONALS The Interprofessional Division of the American College of Rheumatology

Adalimumab (Humira®)

Adalimumab is a monoclonal antibody that binds to the p55 and p75 tumor necrosis factor alpha (TNF- $\alpha$ ) receptors and blocks the binding of TNF- $\alpha$  to cell surfaces.<sup>M</sup>

# Adalimumab (Humira®) Resources from Manufacturer

Patient Medication Guide Full Prescribing Information Patient Support Program Financial Assistance

# Adalimumab-atto (AmjevitaTM) Resources from Manufacturer

<u>Medication guide</u> <u>Full prescribing guide</u> <u>Patient Support Program</u> <u>Financial Assistance</u>

# FDA-Approved Indications and Dosing in Rheumatology

### Adalimumab is indicated for:

- Rheumatoid arthritis (RA) in adults
- Juvenile idiopathic arthritis in patients  $\geq$ 2 years of age (JIA)
- Psoriatic arthritis (PsA) in adults
- Ankylosing spondylitis (AS) in adults
- Nonradiographic axial spondyloarthritis\*
- Refractory sarcoidosis\*
- Arthritis associated with inflammatory bowel disease\*
- Non-infectious uveitis in adults and children ≥ 2 years of age

### \*off-label indication

Adalimumab-atto (Amjevita) is a biosimilar to adalimumab (Humira). It was approved by the US FDA in 2016 and is available in the US as of 01/31/2023. Approved indications in rheumatology, dosing, warnings/precautions, adverse reactions, and administration and storage listed also apply to adalimumab-atto (Amjevita).

continued

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# FDA-Approved Indications and Dosing in Rheumatology continued

## Subcutaneous dosing

- RA, PsA, and AS (adults): Inject 40 mg under the skin every 14 days
- Non-infectious uveitis: 80 mg as a single dose under the skin on day 1 and then 40 mg every 14 days starting day 8 after initial dose
- Pediatric JIA (weight-based dosing)

Weight	Dosing
10 – 15 kg (22 – 33 lbs)	Inject 10 mg under the skin every 14 days
15 – 30 kg (33 – 66 lbs)	Inject 20 mg under the skin every 14 days
≥ 30 kg (66 lbs +)	Inject 40 mg under the skin every 14 days

# Contraindications

None

## Warnings and Precautions

- 1. Serious infections including tuberculosis and invasive fungal infections avoid starting during active infection. If an infection develops, monitor carefully and hold therapy if serious.
- 2. Demyelinating disease-exacerbation or new onset
- 3. Congestive heart failure-worsening or new onset
- 4. Malignancies have been reported
- 5. Hepatitis B virus reactivation
- 6. Pancytopenia or aplastic anemia
- 7. Anaphylaxis and other serious allergic reactions
- 8. Formation of autoantibodies and lupus-like syndrome
- 9. Avoid live vaccines while on treatment

# Adverse Reactions (>10%)

- Infections including upper respiratory tract infections and sinusitis
- Injection-site reaction
- Headache
- Skin rash

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## **Medication Strength and Preparations**

- Single-dose prefilled auto-injector (Humira Pen): 40 mg/0.4mL, 40 mg/0.8mL (contains citrate), and 80 mg/0.8mL
- Single-dose prefilled autoinjector (Amjevita SureClick): 40 mg/0.8mL
- Single-dose prefilled syringe (Humira): 80 mg/0.8mL, 40 mg/0.8mL (contains citrate), 40 mg/0.4mL, 20 mg/0.4mL (contains citrate), 20 mg/0.2 mL, 10 mg/0.2mL (contains citrate), 10 mg/0.1mL
- Single-dose prefilled syringe (Amjevita): 20 mg/0.4mL and 40 mg/0.8mL

## **Medication Administration and Storage**

- Store in original carton to protect from light
- Store in refrigerator at 2°C to 8°C (36°F to 46°F) do not freeze
- Before injecting, allow injection to warm to room temperature for 15 30 minutes prior to administration
- Inject subcutaneously into front of thigh or abdomen (avoid injecting within 2 inches of navel)
- Do not administer into tender, bruised, red or hard skin
- Rotate injection sites ( $\geq 1$  inch apart)
- Safe at room temperature (defined as up to 25°C (77°F)) for up to 14 days
- Adalimumab citrate-free and adalimumab-atto preparations do not contain natural rubber latex

# **Additional Considerations**

- For the treatment of rheumatoid arthritis, consider increasing dose to 40 mg under the skin every 7 days or 80 mg every 14 days if insufficient response
- Citrate-free preparations including adalimumab-atto may result in less burning upon injection

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