Adalimumab (Humira®)

Adalimumab is a monoclonal antibody that binds to the p55 and p75 tumor necrosis factor alpha (TNF-α) receptors and blocks the binding of TNF-α to cell surfaces.™

Adalimumab (Humira®) Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Patient Support Program
Financial Assistance

Adalimumab-atto (AmjevitaTM) Resources from Manufacturer

Medication guide
Full prescribing guide
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FDA-Approved Indications and Dosing in Rheumatology

Adalimumab is indicated for:

- Rheumatoid arthritis (RA) in adults
- Juvenile idiopathic arthritis in patients ≥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

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

ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

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 (≥ 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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