

ASSOCIATION & 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- α) receptors and blocks the binding of TNF- α to cell surfaces.TM

Adalimumab (Humira®) Resources <u>Patient Medication Guide</u> <u>Full Prescribing Information</u>	Adalimumab-adaz (Hyrimoz [™]) Resources Medication guide Full prescribing guide		
Patient Support Program Financial Assistance	Patient Support Program Financial Assistance		
Adalimumab-afzb (Abrilada™) Resources	Adalimumab-aacf (Idacio™) Resources		
<u>Medication guide</u> <u>Full prescribing guide</u> <u>Patient Support Program</u> <u>Financial Assistance</u>	<u>Medication guide</u> <u>Full prescribing guide</u> <u>Patient Support Program</u> <u>Financial Assistance</u>		
Adalimumab-atto (Amjevita™) Resources	Adalimumab-ryvk (Simlandi™) Resources		
<u>Medication guide</u> <u>Full prescribing guide</u> <u>Patient Support Program</u> <u>Financial Assistance</u>	<u>Medication guide</u> <u>Full prescribing guide</u> <u>Financial Assistance</u>		
Adalimumab-adbm (Cyltezo™) Resources	Adalimumab-aaty (Yuflyma™) Resources		
Cyltezo Medication guide Cyltezo Full prescribing guide	Medication guide Full prescribing guide		
Adalimumab-adbm Medication guide Adalimumab-adbm Full prescribing guide Patient Support Program Financial Assistance	Patient Support Program Financial Assistance		
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Adalimumab-adbm Full prescribing guide Patient Support Program Financial Assistance Adalimumab-bwwd (Hadlima [™]) Resources Medication guide Full prescribing guide Patient Support Program	Financial Assistance Adalimumab-aqvh (Yusimry™) Resources 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 \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

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

	High Concentration (100 mg/mL)			
Drug	80 mg/0.8 mL	40 mg/0.4 mL	20 mg/0.2mL	10 mg/0.1 mL
Adalimumab	Pen, Syringe	Pen, Syringe	Syringe	Syringe
Adalimumab-atto (Amjevita)	Pen, Syringe	Pen, Syringe	Syringe	_
Adalimumab-adbm (Cyltezo)^	-	Pen, Syringe	_	-
Adalimumab-bwwd (Hadlima)	-	Pen, Syringe	-	_
Adalimumab-adaz (Hyrimoz)	Pen, Syringe	Pen, Syringe	Syringe	Syringe
Adalimumab-ryvk (Simlandi)	_	Pen, Syringe	_	_
Adalimumab-aaty (Yuflyma)	Pen	Pen, Syringe	Syringe	_

	Low Concentration (50 mg/mL)			
Drug	N/A	40 mg/0.8 mL	20 mg/0.4mL	10 mg/0.2 mL
Adalimumab^*	_	Pen*, Syringe*	Syringe*	Syringe*
Adalimumab-afzb (Abrilada)	-	Pen, Syringe	Syringe	Syringe
Adalimumab-atto (Amjevita)	_	Pen, Syringe	Syringe	Syringe
Adalimumab-adbm (Cyltezo)^	-	Pen, Syringe	Syringe	Syringe
Adalimumab-bwwd (Hadlima)*	_	Pen*, Syringe*	_	_
Adalimumab-fkjp (Hulio)	-	Pen, Syringe	Syringe	_
Adalimumab-adaz (Hyrimoz)	_	Pen, Syringe	Syringe	Syringe
Adalimumab-aacf (Idacio)	_	Pen, Syringe	_	_
Adalimumab-aqvh (Yusimry)	_	Pen, Syringe	_	_

*Contains citrate ^Contains latex

continued



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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)
- Adalimumab, adalimumab-atto, adalimumab-adbm, adalimumab-adaz, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, adalimumab-aqvh: Safe at room temperature (defined as up to 25°C (77°F)) for up to 14 days
- Adalimumab-aacf: Safe at room temperature (defined as up to 25°C (77°F)) for up to 28 days
- Adalimumab-afzb, adalimumab-aaty: Safe at room temperature (defined as up to 30°C (86°F)) for up to 30 days
- Adalimumab citrate-free, adalimumab-aacf, adalimumab-adaz, adalimumab-afzb, adalimumab-aqvh, adalimumab-atto, adalimumab-bwwd, adalimumab-fjkp, adalimumab-ryvk: 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 may result in less burning upon injection

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DISCLAIMER: The information contained in this biologic reference guide is offered solely for purposes of providing health care professionals with a quick and initial reference. Before prescribing or administering any drug contained in this biologic reference guide, health professionals should read the manufacturer's complete prescribing information in order to be informed of the various clinical considerations to be taken into account. The American College of Rheumatology is providing this information as a benefit and service in furtherance of its educational mission. By providing this information, ACR is not endorsing or recommending any of the listed companies or any of their drugs or other products. The information contained in the biologic reference guides reflect the conclusions of the individual companies and not those of the ACR which specifically disclaims any responsibility or liability for the use of such information and/or for the performance of any of the drugs listed in this biologic reference guide.