

## Etanercept (Enbrel®)

Etanercept is a dimeric, DNA-derived protein that binds to the p75 tumor necrosis factor receptor and blocks the binding of TNF- $\alpha$  and TNF- $\beta$  to cell surfaces.

### Resources from Manufacturer

[Patient Medication Guide](#)  
[Full Prescribing Information](#)  
[Patient Support Program](#)  
[Financial Assistance](#)

### FDA-Approved Indications and Dosing in Rheumatology

#### Etanercept is indicated for:

- Ankylosing spondylitis (AS)
- Polyarticular juvenile idiopathic arthritis (JIA) in patients  $\geq 2$  years of age
- Plaque Psoriasis (Ps) in patients  $\geq 4$  years of age
- Psoriatic arthritis (PsA)
- Rheumatoid arthritis (RA)

#### Subcutaneous Dosing

- Adult PsA, RA, JIA, and AS: Inject 50 mg under the skin every 7 days
- Pediatric JIA: Inject 0.8 mg/kg under the skin every 7 days (maximum 50 mg per week)

### Contraindications

 Sepsis

### 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. Lupus-like syndrome
9. Autoimmune hepatitis
10. Caution in patients with moderate to severe alcoholic hepatitis
11. Avoid use in patients with granulomatosis with polyangiitis
12. Avoid live vaccines while on treatment

### Adverse Reactions (>5%)

- Infections
- Injection site reaction

## Medication Strength and Preparations

- Single-dose pre-filled syringe: 25 mg/0.5mL, 50mg/mL
- Single-dose prefilled auto-injector [Enbrel SureClick]: 50 mg/mL
- Single-dose prefilled cartridge for use with reusable AutoTouch device [Enbrel Mini]: 50 mg/mL
- Solution in single-dose vial: 25mg/0.5mL [only latex-free formulation]

## 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 30–90 minutes prior to administration
- Inject subcutaneously into front of thigh, lower abdomen [avoid injecting within 2 inches of navel], or outer area of upper arm
- Do not administer into tender, bruised, red or hard skin
- Rotate injection sites (≥ 1 inch apart)
- Safe at room temperature [defined as 20°C and 25°C (68°F and 77°F)] for up to 30 days
- Prefilled syringe, SureClick autoinjector and Mini cartridge are not made with natural rubber latex

### Updated June 2024—ARP Practice Committee

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.