



## News Articles, Dermatology, Pharmacology, FDA Update

### FDA approves TNF inhibitor to treat children with chronic plaque psoriasis

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The Food and Drug Administration (FDA) recently approved Enbrel (etanercept), a tumor necrosis factor (TNF) inhibitor, as the first systemic treatment for chronic moderate to severe plaque psoriasis in patients 4 years of age and older. Enbrel is given once a week as a subcutaneous injection.

Other drugs approved for pediatric patients with chronic plaque psoriasis are limited to topical agents, and they are not labeled for use in children under 12 years of age.

Psoriasis is a chronic inflammatory disease primarily affecting the skin and joints. Plaque psoriasis is the most common subtype. Approximately 20% of patients have moderate to severe disease.

Multiple co-morbidities exist, including depression/suicide, autoimmune disease, cardiovascular disease and metabolic syndrome. The impact on patients' quality of life has been found to be comparable to that associated with cancer, arthritis and other serious chronic diseases. Childhood-onset psoriasis correlates with impaired social development, sleep problems and substance abuse.

Enbrel's approval for pediatric plaque psoriasis was supported by a 48-week randomized, double-blind, placebo-controlled efficacy trial in 211 subjects ages 4-17 years. After 12 weeks of therapy, more Enbrel than placebo-treated subjects (57% vs. 11%;  $p < 0.0001$ ) achieved a 75% reduction in their baseline Psoriasis Area and Severity Index score.

The observed adverse reactions were similar in frequency and type to those seen in adults, which included infections and injection site reactions. No deaths, malignancies or opportunistic infections were reported.

The drug label includes a warning for serious infections and for lymphoma and other malignancies, some fatal, in children and adolescents treated with TNF blockers, including Enbrel. The manufacturer conducts enhanced postmarketing surveillance for malignancies in patients under 30 years of age, which the FDA requires for all TNF blockers.

#### Resources

- [More information on Enbrel including product labeling](#)
- [The FDA Drug Safety Communication on Tumor Necrosis Factor \(TNF\) blockers and risk for pediatric malignancy](#)