

Taltz[®] (ixekizumab) – Expanded indication

- On March 30, 2020, <u>Eli Lilly announced</u> the <u>FDA approval</u> of <u>Taltz (ixekizumab)</u>, for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
 - Taltz was previously approved for this indication in adult patients only.
- Taltz is also approved for the treatment of adult patients with active psoriatic arthritis and adult
 patients with active ankylosing spondylitis.
- The approval of Taltz for the expanded indication was based on a randomized, double-blind, placebo-controlled trial in 171 pediatric patients 6 to less than 18 years of age, with moderate-to-severe plaque psoriasis. Response to treatment was assessed at 12 weeks of therapy and was defined by the proportion of patients who achieved a static Physician Global Assessment (sPGA) score of "0" (clear) or "1" (almost clear) with at least a 2 point improvement from baseline and the proportion of patients that achieved a reduction in Psoriasis Area and Severity Index (PASI) score of at least 75% (PASI 75) from baseline.
 - The sPGA endpoint was achieved in 81% of patients receiving Taltz vs. 11% receiving placebo.
 - The PASI 75 endpoint was achieved in 89% of patients receiving Taltz vs. 25% receiving placebo.
- The recommended dose of Taltz for the treatment of pediatric plaque psoriasis is based on the weight. Taltz is administered by subcutaneous injection every 4 weeks.

Pediatric patient's weight	Starting dose (week 0)	Dose every 4 weeks thereafter
Greater than 50 kg	160 mg (two 80 mg injections)	80 mg
25 to 50 kg	80 mg	40 mg
Less than 25 kg	40 mg	20 mg

Refer to the Taltz drug label for dosing for all its other indications.



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