

Dupixent[®] (dupilumab) – Expanded indication

- On June 7, 2022, [Sanofi](#) and [Regeneron](#) announced the [FDA approval](#) of [Dupixent \(dupilumab\)](#), for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
 - Dupixent was previously approved for this indication in patients 6 years of age and older.
- Dupixent is also approved:
 - As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
 - As add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis
 - For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis.
- The approval of Dupixent for the expanded indication was based on a randomized, double-blind, placebo-controlled study in 162 patients 6 months to 5 years of age, with moderate-to-severe atopic dermatitis. Patients received Dupixent plus topical corticosteroids or placebo plus topical corticosteroids. The primary endpoint was the proportion of patients with an Investigator's Global Assessment (IGA) 0 (clear) or 1 (almost clear) at week 16.
 - IGA 0 or 1 was achieved in 28% and 4% of patients who received Dupixent and placebo, respectively (treatment difference 24, 95% CI: 13, 34).
- The recommended dosage of Dupixent for pediatric patients 6 months to 5 years of age weighing 5 kg to less than 15 kg is 200 mg (one 200 mg injection) subcutaneously every 4 weeks. For pediatric patients 6 months to 5 years of age weighing 15 kg to less than 30 kg is 300 mg (one 300 mg injection) every 4 weeks.
 - Refer to the Dupixent drug label for dosing for all its other uses and indications.