

Nemluvio® (nemolizumab-ilto) - New indication

- On December 13, 2024, <u>Galderma announced</u> the FDA approval of <u>Nemluvio (nemolizumab-ilto)</u>, for the treatment of adults and pediatric patients 12 years of age and older with <u>moderate-to-severe atopic dermatitis</u> in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
- Nemluvio is also approved for the treatment of adults with prurigo nodularis.
- The approval of Nemluvio for the new indication was based on two randomized, double-blind, placebo-controlled trials (ARCADIA 1 and ARCADIA 2) in a total of 1,728 patients 12 years of age and older with moderate-to-severe atopic dermatitis not adequately controlled by topical treatments. In both studies, the co-primary endpoints were the: (1) proportion of patients with an Investigator's Global Assessment (IGA) success (defined as an IGA of 0 [clear] or 1 [almost clear] and a ≥ 2-point reduction from baseline) at week 16; and (2) proportion of patients with Eczema Area and Severity Index (EASI)-75 (≥ 75% improvement in EASI from baseline) at week 16.
 - In ARCADIA 1, IGA success was achieved in 36% and 25% of patients receiving Nemluvio and placebo, respectively (difference of 12, 95% CI: 6, 17). EASI-75 was achieved in 44% and 29% of patients, respectively (difference 15, 95% CI: 9, 21).
 - In ARCADIA 2, IGA success was achieved in 38% and 26% of patients receiving Nemluvio and placebo, respectively (difference of 12, 95% CI: 6, 19). EASI-75 was achieved in 42% and 30% of patients, respectively (difference 12, 95% CI: 6, 19).
- The most common adverse reactions (≥ 1%) with Nemluvio use for atopic dermatitis were headache (including migraine), arthralgia, urticaria, and myalgia.
- The recommended dose of Nemluvio for the treatment of atopic dermatitis is an initial dose of 60 mg (two 30 mg subcutaneous injections), followed by 30 mg subcutaneous injection given every 4 weeks.
 - After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a subcutaneous dosage of 30 mg every 8 weeks is recommended.



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