Palforzia® (peanut [Arachis hypogaea] allergen powder-dnfp) – Expanded indication

- On July 26, 2024, the FDA approved Aimmune Therapeutics Palforzia (peanut [*Arachis hypogaea*] allergen powder-dnfp), for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 1 through 17 years. Up-dosing and maintenance may be continued in patients 1 year of age and older.
    - Palforzia is now approved for the treatment of children 1 through 3 years of age. Previously, Palforzia was approved for children ages 4 through 17 years of age.
    - Palforzia is to be used in conjunction with a peanut-avoidant diet.
    - Palforzia is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- The approval of Palforzia for the expanded use was based on a randomized, double-blind, placebo-controlled study in 146 children with peanut allergy aged 1 through 3 years. The primary efficacy endpoint was the percentage of subjects tolerating a single dose of 600 mg peanut protein in the exit double-blind, placebo-controlled food challenge (DBPCFC) with no more than mild allergic symptoms after 6 months of maintenance treatment.
    - At the exit DBPCFC, response rates were 73.5% in the Palforzia group vs. 6.3% in the placebo group (treatment difference, 67.2%; 95% CI: 50.0, 84.5; $p < 0.0001$).
- Palforzia carries a boxed warning for anaphylaxis.
    - Because of the risk of anaphylaxis, Palforzia is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Palforzia REMS.
- The most common adverse reactions (≥ 5%) with Palforzia use in children 1 to 3 years of age were cough, sneezing, rhinitis, nasal congestion, throat irritation, wheezing, abdominal pain, vomiting, diarrhea, oral pruritus, oropharyngeal pain, urticaria, rash, pruritis, and perioral dermatitis.
- The recommended dose of Palforzia for the treatment of the expanded indication is administered orally in 3 sequential phases: initial dose escalation, up-dosing, and maintenance.
    - Refer to the Palforzia drug label for additional dosing recommendations for all indications.