

U.S. Food and Drug Administration approved Palforzia on 1/31/20

- ages 4 through 17 years
- Palforzia is designed to reduce the frequency and severity of allergic reactions for those suffering with peanut allergy who may accidentally be exposed to peanuts.
- Palforzia works like other oral immunotherapies: patients ingest controlled, increasing amounts of the drug over a period of time. The result is that the patient's immune system tolerates a larger amount of peanut before reacting.
- Treatment with Palforzia consists of three phases
  - Initial Dose Escalation -
  - Up-Dosing
  - Maintenance
- Patients are at highest risk during and after the Initial Dose Escalation and the first dose of each Up-Dosing level so always done in the office setting
- Patients or their parents or caregivers must also be counseled on the need for the patients to have injectable epinephrine available for immediate use at all times, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis.
- During Up-Dosing, if the patient tolerates the first dose of an increased dose level, the patient may continue that dose level daily at home
- After a patient completes all Up-Dosing levels, a period which lasts six months or longer, the patient continues to take a daily therapeutic dose to maintain desensitization
- Palforzia is a powder that is manufactured from peanuts and packaged in pull-apart color-coded capsules for Dose Escalation and Up-Dosing, and in a sachet for maintenance treatment
- The powder is emptied from the capsules or sachet and mixed with a small amount of semisolid food - such as applesauce, yogurt, or pudding - that the patient then consumes
- After 6 months of Maintenance dosing - 67.2% of Palforzia recipients tolerated a 600 mg dose of peanut protein (~2 whole peanuts) in the challenge, compared to 4.0% of placebo recipients
- Palforzia itself increased the risk of allergic reactions and use of emergency epinephrine shots during the 12 months of treatment preceding the food challenge.
  - About 14% of Palforzia users had systemic allergic reactions during the treatment period, versus 3% of those in the placebo group.
  - The most commonly reported side effects of Palforzia were abdominal pain, vomiting, nausea, tingling in the mouth, itching (including in the mouth and ears), cough, runny nose, throat irritation and tightness, hives, wheezing and shortness of breath and anaphylaxis

- Those that experienced reactions, 98.2% were classified as “mild” or “moderate” and included nausea, itchiness in the throat, and vomiting.
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- Palforzia, which will carry a list price of \$890 per month—the company will offer an assistance program to drop the patient’s share of the cost to as low as \$20
- Aimmune says the treatment isn’t intended to allow allergy patients to begin eating peanut-butter sandwiches, but rather to reduce the risk of reactions after accidental exposures
- Children who take the new therapy are still advised to continue to avoid peanuts and to have access to emergency epinephrine shots, such as EpiPen, in case of reactions.