



FAQ for PALFORZIA - Peanut Oral Immunotherapy

PALFORZIA is the first FDA-approved oral immunotherapy for treatment of peanut allergy for children between ages 4 and 17 years. This handout includes frequently asked questions regarding this product to help you make an informed decision whether this therapy is right for your child. It is *not yet available* to prescribe. PALFORZIA will be only available through a restricted program called Risk Evaluation and Mitigation Strategy (REMS). Dispensing pharmacies, physicians, and patients and their families must be enrolled in the REMS program and receive appropriate training prior to initiation.

What is peanut oral immunotherapy (pOIT)?

Peanut OIT involves feeding increasing amounts of peanut with the goal of increasing the threshold dose so your child is less reactive to accidental ingestion of peanut, such as via cross-contact. OIT involves a **life-long** commitment with daily dosing. **OIT is not a cure.** Your child will still be allergic to peanut. You will always need to continue to carry epinephrine injectors, carefully read food labels, avoid other forms of peanuts, and have an updated anaphylaxis/emergency plan. It is *not* expected that OIT will lead to ingestion of peanut without limitation.

Initial dosing: At the allergist's office, your child will ingest increasing doses of peanut powder starting at a tiny amount and then undergo prolonged observation. Your child will go home and consume the peanut powder until the next office visit (usually in 1-3 days).

Build-up phase: Your child will be given an increased dose of peanut powder at the allergist's office and kept under observation. Then, your child will go home and consume that amount daily until the next office visit. If no reactions, children will go through 11 build-up doses. This can take between 6-12 months.

Maintenance phase: Your child will have daily ingestion of peanut powder (maintenance dose is equivalent to a single peanut.)

How often will my child need to visit the allergist?

During build-up, your child will need to come to the office **every two weeks** for a minimum of 6 months; the build-up phase for most patients takes 8-9 months. Each build-up visit will take a **minimum of 2 hours**.

During the maintenance phase, your child will be seen by the allergist at least **every 3 months**. If a child *misses 3 or more consecutive days* of PALFORZIA, resumption should be done under medical supervision.

How is PALFORZIA given?

PALFORZIA is peanut powder packaged inside a capsule. Every day, the capsule will be opened and mixed into other food such as applesauce or pudding. It is best for your child to have eaten other foods and not take PALFORZIA on an empty stomach. Unlike peanut products purchased over the counter, PALFORZIA is a pharmaceutical-grade powder with precise and consistent amounts of key peanut proteins.

How effective is PALFORZIA?

In a study of nearly 500 children, two-thirds who received PALFORZIA could eat the equivalent of two peanuts — and some three or four — compared to just 4% of patients given a dummy drug.

What are the side effects of PALFORZIA?

Nearly all patients reported adverse events during the clinical trials. The most common side effects are itchy mouth/throat/ears and digestive symptoms such as abdominal pain, vomiting, and cramping. Often, these reactions are mild and can be treated with antihistamines.



Can severe allergic reactions (anaphylaxis) happen with PALFORZIA?

Severe allergic reactions (anaphylaxis) can occur more often during build-up but also at any time. Most concerning is that many of these severe reactions are unpredictable and can occur to a previously tolerated dose. Patients on PALFORZIA had *three-fold increase in anaphylaxis* frequency (9.4% vs 3.8% in placebo group) and *double the rate of epinephrine use* compared to placebo.

The risk of anaphylaxis increases in the presence of these cofactors:

- Exercise
- Hot water exposure
- Intercurrent illness
- Fasting
- Menstruation
- Uncontrolled asthma

Please speak to your allergist about these situations.

Can my child exercise while on PALFORZIA?

Yes, your child can exercise BUT **must not exercise 1 hour prior and 3 hours after the dose is taken.** This is a risk factor for severe allergic reactions and is a major consideration for children involved in high-level sport activities.

Can my child stop and re-start PALFORZIA whenever I want?

No. Starting and stopping without your allergist's guidance can be extremely dangerous and result in severe allergic reactions.

Why do patients stop PALFORZIA?

During clinical trials, 20% of children withdrew from the studies due to side effects which were mostly digestive, including persistent stomach pain, nausea and/or vomiting. In addition, aversion to the taste and smell of the product is tough to overcome, and some children refused to continue the therapy.

Some patients on PALFORZIA can develop eosinophilic esophagitis (EoE). It is an allergic disease of the esophagus that causes difficulty swallowing, vomiting, abdominal pain, and weight loss. If this occurs, then PALFORZIA must be stopped.

What is the cost of PALFORZIA?

The list price of PALFORZIA is \$890 per month, or nearly \$11,000 per year. This does not include the cost of allergist's visits or medical calls. Currently, insurance coverage is unknown.

Who is a good candidate for PALFORZIA?

Patients who are compliant and maintain appropriate caution regarding their peanut allergy. They also need to have well-controlled asthma and a flexible schedule.

Who would not be a suitable candidate for PALFORZIA?

Patients who are nervous, anxious, and extremely fearful of ingesting peanuts are not good candidates. Daily ingestion of the allergen can have worsening effects on some patients' anxiety. Patients with poorly or uncontrolled asthma or other compromised lung function, mast cell disease, cardiovascular disease, and/or eosinophilic esophagitis are also not suitable candidates for this therapy.

New research is actively looking at various types of food immunotherapy that may be a better fit for your child. If you are interested in participating in clinical trials, please go to <http://www.SeattleAllergy.org> to learn more.

Now what do I do to get started?

If you are interested in starting PALFORZIA for your child or learning more, please schedule an appointment with one of our allergy providers to discuss further.