

PALFORZIA

- Approved for use in ages 4 through 17 years old only.
- 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 is a powder that is manufactured from peanuts and packaged in pull-apart color-coded capsules. 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
- Palforzia works like other oral immunotherapies: patients ingest controlled, increasing amounts of the drug over a period of time. The desired 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 (IDE)**– consists of 5 increasing doses spaced 20-30 minutes apart all in a morning office visit with a 60 minute wait after the last dose.
 - **Up-Dosing** – starts immediately after initial dose escalation (next day) and consists of 11 biweekly office visits of escalating single doses that the patient then continues at home daily
 - **Maintenance Dosing** after all levels of the Up-Dosing have been completed, using the last dose 300 mg taken once daily indefinitely
- Patients are at highest risk during and after the Initial Dose Escalation and the first dose of each Up-Dosing level, so these are always done in the office setting
- Patients/Parents must be counseled on the need for the patient to have injectable epinephrine available for immediate use, 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 must continue that dose level daily at home
- After a patient completes all Up-Dosing levels, a period which will last about six months or longer, the patient continues indefinitely to take a daily therapeutic dose to maintain desensitization
- 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.
- This 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

Additional Notes:

For the initial visit (IDE) plan on being in the office for about 4 hours. Please bring anything that will make you and your child comfortable at the appointment. Bring your injectable epinephrine device (so you have it for the drive home afterwards) and a soft food, such as applesauce yogurt, or pudding for mixing the doses. Bring also other snacks or water you may want for those hours. Please also feel free to bring activities that will keep you both entertained during your wait.

Once your child has passed the Initial dosing visit, he/she will return the following day for the first Up-Dosing. This visit will last about 1 hour and will consist of one dose and a wait of 60 minutes afterwards to observe. Following successful dosing, your child will continue taking the new dose at home for the next 2 weeks. We will supply the doses necessary for these home doses at this visit and we would ask you to bring along a small cooler to transport the dose boxes home. The boxes come with complete instructions. Keep them in a cool dry place (refrigerator is best) in their original packaging until ready to use. Do not freeze. Try to dose daily at the same time each day. DO NOT give your child a dose on the day he/she is scheduled for an office visit (for Up-Dosing).

Doses at home often consists of various capsules that together make up the total dose for the day. You will open and combine these capsules as directed, emptying their contents into the soft food (yogurt, applesauce, or pudding) and mixing well. Food can be at refrigerator or room temperature but not heated or in liquid form. Use just the amount of food for the mixture that your child will consume in two to three spoonfuls total. Monitor you child for 1 hour after dosing each day for any allergic symptoms. If you miss more than one dose, contact our office. Do not take additional doses on the same day to make up for missed doses. Do not give you child a dose if they are very hot or have just participated in any strenuous physical activity, like a game or sport, and they still have a high heart rate. Also, do not allow you child to participate in sports or other strenuous activity or take a hot bath/shower within 3 hours of taking a dose.