

The Allergy & Asthma Clinic

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Newsletter

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First Drug to treat and reduce the risk of Children's Peanut Allergies Approved by the FDA

Peanut allergy is a condition in which the body's immune system mistakenly identifies even small amounts of peanut as harmful. Allergic reactions to peanut are unpredictable in occurrence and in how they present, with some individuals experiencing severe reactions from exposure to even trace amounts. Physical symptoms can develop within seconds of exposure and may include skin reactions (e.g., hives, redness or swelling), digestive discomfort, or more dangerous reactions, such as constriction of the throat and airways, and loss of adequate blood flow to vital organs of the body. Antihistamines and epinephrine can be used to treat



allergic reactions, but severe reactions can be fatal even with appropriate, prompt treatment.

When used in conjunction with peanut avoidance, Palforzia provides an FDA-approved treatment option to help reduce the risk of allergic reactions in children with peanut allergy.

“Peanut allergy affects approximately 1 million children in the U.S. and only 1 out of 5 of these children will outgrow their allergy,” said Dr. Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research, in the agency’s statement. “Even with strict avoidance, inadvertent exposures can and do occur... Palforzia provides an FDA-approved treatment option to help reduce the risk of these allergic reactions in children with peanut allergy.” It is important to know that Palforzia cannot be used for the emergency treatment of allergic reactions, including anaphylaxis.

How the drug works: Palforzia treatment includes three phases. The first day of treatment involves escalating doses given over 3-5 hours. The up-dosing phase is next and typically consists of 11 increasing levels of dosage over several months. Both phases are administered under the supervision of a medical professional in a healthcare setting to manage possible adverse reactions. If successful, that leads to the maintenance phase, which can be done at home.

Palforzia’s effectiveness was supported by a randomized, double-blind, placebo-controlled study done in the United States, Canada, and Europe in approximately 500 people with peanut allergies. The drug’s safety was tested in two studies with approximately 700 people. The most common side effects were abdominal pain, vomiting, nausea, tingling in the mouth, cough, runny nose, throat irritation and tightness, hives, wheezing, and shortness of breath and anaphylaxis.

Before treatment with Palforzia is considered, it is important to make sure that allergy skin and blood tests are up to date, including component studies to peanut, which provide us with very important predictors of reactivity or tolerance to peanut.

Palforzia will only be available through specially certified healthcare providers, health care settings, and pharmacies to patients who are enrolled in the Risk Evaluation and Mitigation Strategy REMS program. The FDA is requiring that healthcare providers who prescribe Palforzia - and healthcare settings that dispense and administer Palforzia - are educated on the risk of anaphylaxis associated with its use.

We will provide you with additional updates as more information about this treatment becomes available.

To allow the next phase of our remodel, the office will be closed on Friday, February 28, 2020 and Saturday, February 29, 2020. Thank you for your patience.