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FDA Approves First Drug to Treat Peanut Allergies in Kids

Children are exposed to controlled amounts of Palforzia until they can tolerate the dosage needed to avoid severe allergic reactions.

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Peanut allergy affects roughly 1 million American children, and only one out of five of these children will outgrow their allergy, experts say. But the Food and Drug Administration's (FDA) approval of the first drug to treat this life-threatening allergy may soon make life a little easier for allergic youngsters.

A recent FDA press release announced that Palforzia—a powder manufactured from peanut protein—will help alleviate allergic reactions, including anaphylaxis, in children ages 4 to 17 with a peanut allergy who are accidentally exposed to these nuts. (Anaphylaxis is a serious allergic response that often involves narrowed airways, resulting in difficulty breathing, swelling, hives, lowered blood pressure and, in severe cases, shock.)

The powder is mixed with a small amount of semisolid food, such as applesauce, yogurt or pudding, that the child then consumes.

Children are exposed to controlled dosages of Palforzia until they are able to tolerate 600 milligrams of the peanut protein. Patients receive one initial dose given in a single day and then are given 11 increasing dose levels over the course of about six months.

To offset any potential allergic reactions both the initial dose and the first dose of each increased, (up-dosed) level must be administered in a health care setting under a health care professional's supervision.

Once a patient tolerates the first dose of the drug at an increased level, he or she may continue taking treatment daily at home. If individuals complete all up-dosing levels, they may begin the daily maintenance dose of 600 mg.

Per the FDA, Palforzia will be available only through specially certified health care providers, health care settings and pharmacies for patients enrolled in the Risk Evaluation and Mitigation Strategy program. The agency also requires that providers be educated on the risk of Palforzia-associated anaphylaxis.

In addition, the FDA stipulated that both patients and their parents “must be counseled on the need for 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.”

The most commonly reported side effects of the drug 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.

Additionally, young people with uncontrolled asthma are not cleared to take Palforzia.

For related coverage, read “Breakthrough Treatment Could Protect People With Peanut Allergies” and “A Dose of Peanuts Early in Life Could Prevent an Allergy in Kids.”

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