

What is PALFORZIA?

PALFORZIA is a treatment for people who are allergic to peanuts. PALFORZIA can help reduce the severity of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA may be started in patients aged 4 through 17 years old. If you turn 18 years of age while on PALFORZIA treatment you should continue taking PALFORZIA unless otherwise instructed by your doctor.

PALFORZIA does NOT treat allergic reactions and should not be given during an allergic reaction.

You must maintain a strict peanut-free diet while taking PALFORZIA.

IMPORTANT SAFETY INFORMATION

PALFORZIA can cause severe allergic reactions called anaphylaxis that may be life-threatening.

- **You will receive your first dose in a healthcare setting under the observation of trained healthcare staff.**
- **You will receive the first dose of all dose increases in a healthcare setting.**
- **In the healthcare setting, you will be observed for at least 1 hour for signs and symptoms of a severe allergic reaction.**
- **If you have a severe reaction during treatment, you will need to receive an injection of epinephrine immediately and get emergency medical help right away.**
- **You will return to the healthcare setting for any trouble tolerating your home doses.**

Stop taking PALFORZIA and get emergency medical treatment right away if you have any of the following symptoms after taking PALFORZIA:

- Trouble breathing or wheezing
- Chest discomfort or tightness
- Throat tightness
- Trouble swallowing or speaking
- Swelling of your face, lips, eyes, or tongue
- Dizziness or fainting
- Severe stomach cramps or pain, vomiting, or diarrhea
- Hives (itchy, raised bumps on skin)
- Severe flushing of the skin

Because of the risk of severe allergic reactions, PALFORZIA is only available through a restricted program called the PALFORZIA Risk Evaluation and Mitigation Strategy (REMS) Program. Talk to your healthcare provider for more information about the PALFORZIA REMS program and how to enroll.

You should NOT take PALFORZIA if you have uncontrolled asthma, or if you ever had eosinophilic esophagitis (EoE) or other eosinophilic gastrointestinal disease.

Tell your doctor if you are not feeling well prior to starting treatment with PALFORZIA. Your doctor may decide to delay treatment until you are feeling better. Also tell your doctor about any medical conditions you have and if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal supplements.

Your doctor may decide that PALFORZIA is not the best treatment if:

- You are unwilling or unable to receive (or self-administer) injectable epinephrine.
- You have a condition or are taking a medication that reduces the ability to survive a severe

allergic reaction.

What are the possible side effects of PALFORZIA?

The most commonly reported side effects of PALFORZIA were: stomach pain, vomiting, feeling sick, itching or burning in the mouth, throat irritation, cough, runny nose, sneezing, throat tightness, wheezing, shortness of breath, itchy skin, hives, and/or itchy ears.

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PALFORZIA can cause stomach or gut symptoms including inflammation of the esophagus (called eosinophilic esophagitis). Symptoms of eosinophilic esophagitis can include:

- Trouble swallowing
- Food stuck in throat
- Burning in chest, mouth, or throat
- Vomiting
- Regurgitation of undigested food
- Feeling sick

For additional information on the possible side effects of PALFORZIA, talk with your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information and Medication Guide, including an Important Warning about anaphylaxis.