

**WHAT
SECONDARY
CAREGIVERS
SHOULD
KNOW ABOUT
ADMINISTERING
PALFORZIA**

Palförzia[™]

Peanut (*Arachis hypogaea*)
Allergen Powder-dnfp

Indication & Important Safety Information

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.

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

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, at PALFORZIA.com/static/pi_palforzia.pdf and PALFORZIA.com/static/medguide_palforzia.pdf.

If you're reading this, you have been trusted to care for a child receiving PALFORZIA treatment. Here's what you need to know.

What is PALFORZIA?

PALFORZIA is a prescription medicine derived from peanuts. It 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.

Before giving the child PALFORZIA, please make sure that you have discussed their allergy with their parent or caregiver, have the child maintain a strict peanut-free diet, and are familiar with how to administer their prescribed injectable epinephrine.

How to give PALFORZIA

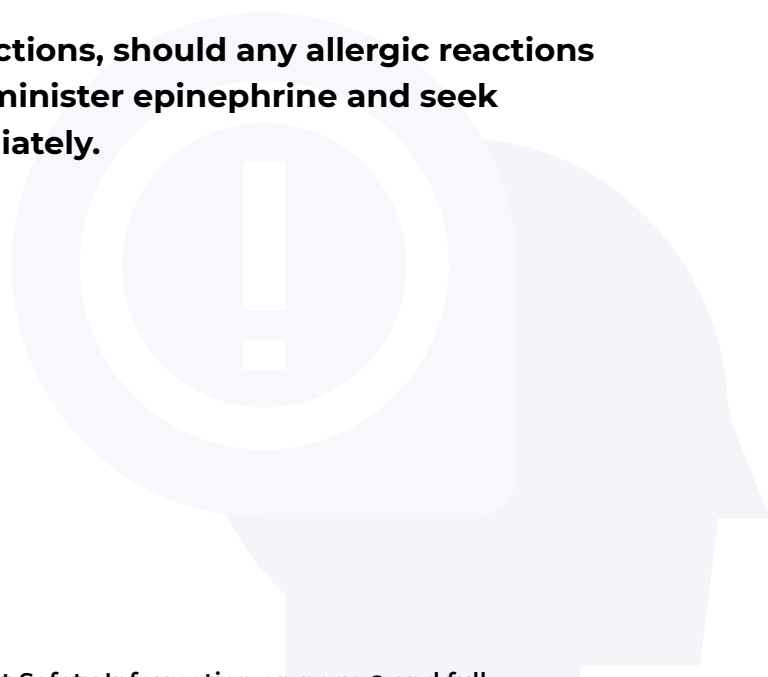
- Give PALFORZIA at the same time daily, with a meal. Open the day's dose and empty the contents into two or three spoonfuls of soft food, like yogurt, applesauce, or pudding that's either cold or at room temperature (not hot). Mix well. Do not mix PALFORZIA with a liquid. Have the child eat it right away.
- The child should consume the dose right away after you mix it.
- Wash your hands immediately after mixing the food together, to make sure there's no PALFORZIA on them.
- Before giving PALFORZIA, make sure the child is cooled down and their heart is beating normally. Do not give PALFORZIA if they have participated in any physical activity that has made them sweaty, breathless, or caused their heart to beat fast, or have just taken a hot bath or shower.
- Keep an eye on the child after they take their dose for at least an hour, and watch for any signs of an allergic reaction.
- Do not let the child participate in any strenuous physical activity or take a hot shower or bath within three hours after receiving their dose.

SIDE EFFECTS ARE AN EXPECTED PART OF TREATMENT

Because PALFORZIA treatment relies on intentional peanut allergen exposure in peanut allergic patients, allergic reactions should be expected. In clinical studies, the most commonly reported side effects 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. For most kids, side effects generally started within 4 minutes of taking PALFORZIA and resolved after about 37 minutes. Monitor the child for reactions and, if necessary, administer medication per your allergist's instructions.

Although uncommon, there is a risk of allergic reactions requiring immediate medical attention, including anaphylaxis, which may be life-threatening. 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.

Per your allergist's instructions, should any allergic reactions occur, be prepared to administer epinephrine and seek medical attention immediately.



DO'S



Continue to have the child carry their injectable epinephrine.



Have the child take their dose of PALFORZIA with a meal at the same time every day; mix it well into a few spoonfuls of a soft food such as applesauce, yogurt, or pudding, that's either cold or at room temperature (not hot and not liquid). Talk to their allergist if you have any questions.



Keep an eye on the child for one hour after they take their dose, in case there are any signs of an allergic reaction.



Keep PALFORZIA in the refrigerator.



If the child misses taking PALFORZIA, contact the child's allergist. Do not take additional doses on the same day to make up for missed doses.



Be aware of certain conditions that may increase the likelihood of an allergic reaction, including having an illness such as a viral infection, being very tired or missing sleep, being stressed, having your menstrual period, exercising, taking certain pain medications such as aspirin or ibuprofen, or drinking alcohol.

DON'TS



Do not have the child eat peanuts or peanut products as part of their diet.



Do not give the child their daily dose of PALFORZIA on the day of an appointment, since they will be receiving some from their allergist.



Do not take more than one dose of PALFORZIA in a single day.



Do not give any more doses if the child has missed a dose of PALFORZIA. Instead, contact their allergist for next steps in continuing treatment.



Do not let the child swallow the capsule or inhale the powder.



Do not give the child PALFORZIA if they are very hot or have just participated in any strenuous physical activity, like a game or sport, and still have a high heart rate.



Do not let the child participate in sports or other strenuous physical activity or take a hot bath or shower within three hours after taking PALFORZIA.



LEARN MORE ONLINE

Visit PALFORZIA.com to learn more.



GET IN TOUCH WITH US

Give us a call and we'll be happy to answer your questions.
1-844-PAL-FORZ (1-844-725-3679)

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