

MEDICATION GUIDE
PALFORZIA
[Peanut (*Arachis hypogaea*) Allergen Powder-dnfp]
Powder for oral administration

Carefully read this Medication Guide before you start taking PALFORZIA and each time you receive a new dose level. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. Talk with your doctor or pharmacist if there is something you do not understand, or you want to learn more about PALFORZIA.

What is the most important information I should know about PALFORZIA?

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 of an allergic reaction 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

Additional symptoms in young children may include;

- Inconsolable crying
- Excessive sleepiness
- Drawing legs up to the stomach

For home administration of PALFORZIA, your doctor will prescribe injectable epinephrine, a medicine you must inject if you have a severe allergic reaction after taking PALFORZIA. Your doctor will train and instruct you on the proper use of injectable epinephrine.

Talk to your doctor and read the epinephrine patient information if you have any questions about the use of injectable epinephrine.

PALFORZIA is only available through a restricted program called the PALFORZIA Risk Evaluation and Mitigation Strategy (REMS) Program. Before you can receive PALFORZIA, you must:

- Enroll in this program.
- Receive education about the risk of a severe allergic reaction (anaphylaxis) by a healthcare provider who practices in a setting that is certified through the REMS program.
- Understand that you will be monitored in a healthcare setting during and after the Initial Dose Escalation and for the first dose of each new Up-Dosing level (see **Dosing Information**).
- Receive education about how to maintain a peanut-free diet. You must attest that you will continue to avoid peanuts at all times.

- Fill the prescription your healthcare provider gives you for the injectable epinephrine. You must attest that epinephrine will be available to you at all times.

Talk to your healthcare provider for more information about the PALFORZIA REMS program and how to enroll.

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 1 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 is intended to gradually decrease your sensitivity to small amounts of peanuts that may be hidden in foods.

PALFORZIA is a medication that must be taken daily to maintain the treatment effect.

PALFORZIA is only intended to treat people with peanut allergy; it is not effective against other food allergies you may have.

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.

Who should not take PALFORZIA?

You should NOT take PALFORZIA if you:

- have uncontrolled asthma.
- ever had eosinophilic esophagitis (EoE) or other eosinophilic gastrointestinal disease.

What should I tell my doctor before taking PALFORZIA?

Tell your doctor if you:

- have any medical conditions.
- are not feeling well prior to starting treatment.
- are taking or have recently taken any other medicines, including non-prescription medicines and herbal supplements. Keep a list of them and show it to your doctor and pharmacist each time you get a new supply of PALFORZIA.
- have had a recent severe or life threatening allergic reaction.
- have a condition or are taking a medication that reduces the ability to survive a severe allergic reaction.
- are pregnant, planning to become pregnant, or breastfeeding.
- are unwilling or unable to receive (or self-administer) injectable epinephrine.

Your doctor may decide that PALFORZIA is not right for you or to delay treatment.

How should I take PALFORZIA?

Dosing Information

There are three different phases of dosing with PALFORZIA – Initial Dose Escalation, Up-Dosing, and Maintenance Dosing.

Initial Dose Escalation:

Ages 1 through 3 years: The first 4 doses (0.5-3mg) of PALFORZIA will be administered on a single day in your doctor's office.

Ages 4 through 17 years: The first 5 doses (0.5-6mg) of PALFORZIA will be administered on a single day in your doctor's office.

If you do not tolerate the Initial Dose Escalation, your doctor may not continue your treatment with PALFORZIA.

Up-Dosing:

If you tolerate the Initial Dose Escalation phase, you will return to your doctor's office the next day to start the Up-Dosing phase.

Ages 1 through 3 years: There are 12 different dose levels of Up-Dosing, starting with PALFORZIA 1 mg (Level 0) and finishing with PALFORZIA 300 mg (Level 11).

Ages 4 through 17 years: There are 11 different dose levels of Up-Dosing, starting with PALFORZIA 3 mg (Level 1) and finishing with PALFORZIA 300 mg (Level 11).

The first dose of each new Up-Dosing level is given in your doctor's office. If you tolerate the first dose of a new dose level, your doctor will ask you to continue to take that dose level every day at home. PALFORZIA should be taken at approximately the same time each day.

During Up-Dosing, you will return to your doctor's office approximately every 2 weeks to be assessed for a new Up-Dosing level. Dose levels cannot be skipped.

Maintenance Dosing:

If you tolerate all dose levels of the Up-Dosing phase, your doctor will ask you to continue taking PALFORZIA at a 300 mg dose every day as Maintenance therapy.

PALFORZIA must be taken every day for it to be effective.

Your doctor will tell you if you can take other medicines with PALFORZIA, such as other allergy treatments, medicines for your stomach, or medicines for any other conditions that you have.

Preparation of PALFORZIA

Prepare and take PALFORZIA exactly as instructed by your doctor.

PALFORZIA is an oral powder that is mixed with refrigerated or room temperature soft food such as applesauce, yogurt, pudding, or other food.

PALFORZIA is provided as either capsules or sachets. PALFORZIA oral powder should be completely emptied from the capsules or sachets into the food before mixing.

Do not swallow the capsules.

Do not breathe in the powder. This could cause breathing problems (worsening of asthma) or cause an allergic reaction.

PALFORZIA must be stored in a refrigerator.

Open the daily dose of PALFORZIA capsule(s) or sachet and empty the full dose of PALFORZIA oral powder on to refrigerated or room temperature soft food such as applesauce, yogurt, or pudding. Do not use liquid (e.g., milk, water, juice) to prepare. Mix well.

The amount of food for mixing must enable you to take the full dose of PALFORZIA in a few spoonfuls.

You should take PALFORZIA immediately after mixing.

Wash your hands immediately after handling PALFORZIA capsules or sachets.

Additional Instructions

Take PALFORZIA at about the same time every day with a meal.

PALFORZIA must be taken every day in order to maintain the treatment effect.

Be aware that allergic reactions are more likely to develop within approximately 1 hour after taking PALFORZIA.

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

Do not take PALFORZIA at home on the days that you visit your doctor for PALFORZIA Up Dosing as your doctor may give you PALFORZIA on these days.

If you miss taking PALFORZIA, contact your doctor. Do not take additional doses on the same day to make-up for missed doses.

Do not exercise or have a hot bath or shower within 3 hours after taking PALFORZIA.

If you have been exercising or have taken a hot bath or shower and are feeling hot, or you are sweating and your heart is beating fast, do not take PALFORZIA until you have cooled down and your heart is beating normally.

Certain conditions may increase the likelihood of an allergic reaction. These include:

- Having an illness such 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
- Drinking alcohol

What are the possible side effects of PALFORZIA?

The most commonly reported side effects were:

Ages 1 through 3 years: Cough, sneezing, runny nose, stuffy nose, throat irritation, wheezing, stomach pain, vomiting, diarrhea, itching or burning in the mouth, throat and mouth pain, hives, rash, itchy skin, and/or rash around the mouth.

Ages 4 through 17 years: 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 that may be life-threatening. Symptoms of allergic reactions to PALFORZIA can include:

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

Additional symptoms in young children may include;

- Inconsolable crying
- Excessive sleepiness
- Drawing legs up to the stomach

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
- Spitting up undigested food
- Feeling sick
- Heartburn or reflux

For additional information on the possible side effects of PALFORZIA, talk with your doctor or pharmacist. You may report side effects to the U.S. Food and Drug Administration (FDA) at 1-800-FDA-1088 or www.fda.gov/medwatch.

How should I store PALFORZIA?

Store PALFORZIA in the original packaging at 2° to 25°C (36° to 77°F). Avoid excessive heat. Do not freeze. Protect from Moisture.

Store in the original packaging until use to protect from moisture.

Keep PALFORZIA out of the reach of children.

Throw away any unused PALFORZIA after the expiration date.

General information about PALFORZIA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PALFORZIA for a condition for which it was not prescribed. Do not give PALFORZIA to other people, even if they have the same symptoms. It may harm them. This Medication Guide summarizes the most important information about PALFORZIA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about PALFORZIA that was written for healthcare professionals. For more information, go to: www.PALFORZIA.com or call 1-844-PALFORZ (1-844-725-3679) (toll-free).

Pregnancy Registry: PALFORZIA has not been studied in women who are pregnant. Aimmune has a registry for women who become pregnant while on PALFORZIA. The purpose of the registry is to follow the health of the mother and her baby. You are encouraged to contact the registry as soon as you become aware of your pregnancy by calling 1-833-AIM-2KNO (1-833-246-2566) or ask your health care provider to contact the registry for you.

Manufactured by: **Aimmune Therapeutics**
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This Medication Guide has been approved by the U.S. Food and Drug Administration.