

PALFORZIA TREATMENT HANDBOOK

**YOUR GUIDE TO UNDERSTANDING
TREATMENT AND HOW TO HELP MAKE
THE PROCESS AS SMOOTH AS POSSIBLE
FOR YOUR FAMILY.**

Palförzia[®]

Peanut (*Arachis hypogaea*)
Allergen Powder-dnfp





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INTRODUCTION

READY TO GET STARTED?

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 is to be used in conjunction with a strict peanut-free diet.

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

PALFORZIA can cause severe allergic reactions called anaphylaxis that 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.



Peanut allergy can be exhausting for your whole family. Beyond avoidance alone, you may wish there was something more you can do.

That something more is PALFORZIA.

While PALFORZIA does not cure peanut allergy, it may help make allergic reactions less severe by gradually decreasing your child's sensitivity to peanuts over time through a process called oral immunotherapy or OIT.

While your child is taking PALFORZIA, they will still need to avoid peanuts and carry injectable epinephrine. PALFORZIA may help them manage their allergy by decreasing their sensitivity to small amounts of peanuts that may be hidden in foods, in the event of an accidental exposure.

IMPORTANT POINTS ABOUT PALFORZIA

PALFORZIA is not a cure for peanut allergy and still requires patients to avoid peanuts in their diet.

PALFORZIA may be started in patients aged 4 through 17 years old. If your child turns 18 years of age while on PALFORZIA treatment, your child should continue taking PALFORZIA unless otherwise instructed by your doctor.

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

PALFORZIA is not effective against other food allergies your child may have.

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

While it's true that PALFORZIA requires a commitment of time and energy, this guide is here to help. Inside, you will find all the information you will need to make the treatment process as smooth as possible.

ENROLLING IN PALFORZIA REMS

Because of the risk of anaphylaxis, 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 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 THIS GUIDE OFFERS

- An explanation of the treatment process
- Key information about how to give your child PALFORZIA
- **Do's** and **Don'ts** for taking PALFORZIA
- Guidelines for what to do if your child has an allergic reaction
- Help and tips for getting your child on board with the process
- Quick guides for your child's caregiving community
- Tips for traveling with PALFORZIA



INDICATION & IMPORTANT SAFETY INFORMATION

INDICATION & IMPORTANT SAFETY INFORMATION

INDICATION

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.

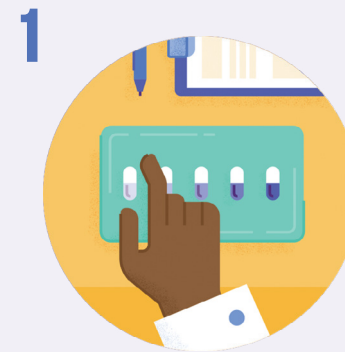
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.



TREATMENT OVERVIEW

THE THREE PHASES OF TREATMENT

Before you get started, it is important to understand the entire treatment process. In the rest of this guide, you will find detailed information for each phase of treatment, so you and your family know what to expect.



INITIAL DOSE ESCALATION ~4 hours

Initial Dose Escalation (IDE) happens in one extended appointment at your child's allergist's office. During this appointment, your child will get five increasing doses of PALFORZIA.



UP-DOSING ~6 months

If your child successfully completes IDE, the next phase is Up-Dosing. During this phase, your child will receive gradually increasing doses of PALFORZIA over the course of about six months. The first dose of each level increase will occur at your child's allergist's office (approximately every two weeks), with the remaining doses of each level being administered at home.



MAINTENANCE – ongoing

If your child successfully passes through all the Up-Dosing steps, they will continue to take a Maintenance Dose of PALFORZIA every day at home. This ongoing dose helps your child tolerate small amounts of peanut protein and is necessary for your child's PALFORZIA treatment to remain effective.



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**INITIAL DOSE
ESCALATION (IDE)**

PREPARING FOR INITIAL DOSE ESCALATION

Starting treatment at your
child’s allergist’s office



Congratulations—you are ready to start the treatment process! The first step will be your child’s Initial Dose Escalation (IDE) appointment. At this appointment, your child’s allergist will attempt to give your child the first five doses of PALFORZIA, if tolerated, with each dose containing a little more peanut allergen than the previous dose. After each dose, your child’s allergist will observe your child for any allergic reactions and respond accordingly.

Think of this appointment as your launchpad: This is where you get your child’s treatment off the ground and on its way.



IDE DOSE CHART

DOSE NUMBER	1	2	3	4	5
AMOUNT OF PEANUT PROTEIN	0.5 mg	1 mg	1.5 mg	3 mg	6 mg

WHAT HAPPENS AT YOUR IDE APPOINTMENT

1

CHECKING IN

Your child's allergist may talk to you and your child about the treatment process and review the Medication Guide with you. They may also take your child's vital signs (temperature, blood pressure, etc.) to make sure they're in good health and ready to start PALFORZIA. The allergist will also make sure that your child is enrolled in the REMS program for PALFORZIA.

2

FIRST DOSE AND OBSERVATION

Once everything is ready, your child's allergist will give your child the first dose of PALFORZIA, mixed into a few spoonfuls of a soft food like yogurt, applesauce, or pudding. Afterward, you'll wait 20–30 minutes to evaluate any potential allergic reactions, and your child's allergist will determine how to proceed.

3

DOSE ESCALATION AND OBSERVATION

After the first dose, there will be four more doses, for a total of five. After each, you will wait 20–30 minutes, so your child's allergist can observe your child for any allergic reactions and make sure they can continue receiving doses. The final dose will be 6 mg of peanut protein, after which the allergist will watch your child for 60 minutes. Should an allergic reaction occur after any of the 5 doses, your child's allergist will treat it accordingly, which may also include discontinuing PALFORZIA.



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. Following PALFORZIA dosing in the clinic, symptoms generally started within a median time of 4 minutes of taking PALFORZIA and resolved after a median time of 37 minutes. Monitor your child for reactions and follow your child's 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 child's allergist's instructions, should any allergic reactions occur, be prepared to administer injectable epinephrine and seek medical attention immediately.

GETTING READY

Tips for making your IDE appointment go more smoothly:



TIMING AND ABSENCES FROM WORK AND SCHOOL

Because the IDE appointment is long, you may need to plan to miss a day of school and work.



TALKING TO YOUR CHILD ABOUT PALFORZIA

Your child should understand why they are taking PALFORZIA and that the goal of treatment is to help gradually decrease sensitivity to small amounts of peanuts that may be hidden in foods. Talk to your child about PALFORZIA treatment and how they are feeling about it.

WHAT YOU MIGHT NEED AT YOUR APPOINTMENT

Since IDE takes at least 4 hours, you may want to bring anything that will make you and your child comfortable at the appointment. Check with your child's allergist to make sure you have everything that their office might require.

WHAT YOU MAY WANT TO BRING



MEDICAL INFORMATION AND PRESCRIPTIONS

- Insurance card
- List of other medications your child may be taking
- Injectable epinephrine



FOOD AND DRINK

- Discuss with your child's allergist if you need to bring any soft food, such as yogurt, applesauce, or pudding, that PALFORZIA can be mixed into
- Any other snack or water for you and your child



ENTERTAINMENT

- Books, games, toys, etc.
- Make a plan with your child and bring activities that will keep you both entertained while you're waiting

WHAT COMES NEXT

If your child has successfully finished the IDE appointment, that means they're ready to move on to the Up-Dosing Phase. Your child's treatment is well on its way! The next step will be to return to your child's allergist's office for the next dose administration.



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UP-DOSING

UP-DOSING

Increasing doses over six months with routine visits to the allergist and continuing treatment at home



Congratulations on completing IDE! Now you are ready to enter the Up-Dosing Phase. In this phase, your child will move through 11 different dosing levels of PALFORZIA.

If IDE was your launchpad for treatment, Up-Dosing is like climbing a staircase. Each step exposes your child to a little bit more peanut allergen—bringing them a little bit closer to the goal of reaching the Maintenance Dose.

WHAT HAPPENS AT YOUR APPOINTMENTS

1

CHECKING IN

Your child's allergist will talk to you and your child about how the last two weeks have gone. Tell the doctor about any allergic reactions your child experienced and if your child needs more epinephrine. If your child is not able to tolerate a specific dose in the way that your child's allergist was expecting, they might recommend that your child stays on that dose for a while longer or go back to a lower dose. This is a normal part of the treatment process, and the PALFORZIA dosing schedule has been designed for these kinds of adjustments.

2

VITAL SIGNS

Your child's allergist will check your child's vital signs (temperature, blood pressure, etc.) to make sure they're ready to try the higher dose.

3

NEW DOSE AND OBSERVATION

Once everything is ready, your child's allergist will give your child the new, higher dose of PALFORZIA. You will wait at least 60 minutes to ensure a higher dose is tolerated. If your child is fine to proceed, they will continue taking this new, higher dose of PALFORZIA at home.

TWO WEEKS OF THE NEW DOSE AT HOME

If the appointment went smoothly, your child will continue taking the new PALFORZIA dose daily for two weeks.

PALFORZIA AT HOME

HOW AT-HOME TREATMENT WORKS

At each appointment, you will either get PALFORZIA directly from your child's allergist's office or your specialty pharmacy will ship it to your home. When you receive it, you'll see that PALFORZIA comes in a little cardboard folder with plastic bubbles around the capsules or in a box with sachets.

Each folder or box will contain all the instructions you will need for administering that dose of PALFORZIA. You can use the following instructions below as a reference, to make sure that you know what to expect and to help you remember the important details.



GETTING AND STORING PALFORZIA

- Your child's allergist may give your first 2–3 doses of PALFORZIA to take home while your specialty pharmacy ships the remaining doses directly to your home. It is also possible that your specialty pharmacy will ship PALFORZIA to your child's allergist's office so that it's waiting for you at each Up-Dosing appointment.
- Store in the original packaging until use to protect from moisture.
- PALFORZIA should be kept in the refrigerator between 36°F–46°F (2°C–8°C). Do not store it in the freezer.
- If PALFORZIA is kept between 36°F–46°F (2°C–8°C), make sure you have a cool place to store it when transporting it.

GIVING YOUR CHILD A DOSE

You will give your child one dose at the same time each day. On days when you are going to an Up-Dosing appointment, do NOT give your child their dose since they will be taking more PALFORZIA at the office.



To give your child a dose, twist to open the capsule or capsules—often there will be more than one, and you will combine their contents. Next, empty them into a soft food such as yogurt, applesauce, or pudding that's either cold or at room temperature (not hot and not liquid) and mix well.



Use just enough soft food so that your child can consume the entire dose in two or three spoonfuls. Your child should consume the dose right away after you mix it.



Wash your hands immediately after handling PALFORZIA so that you do not accidentally spread it around your home. Do not breathe in the powder.



You will need to monitor your child for about an hour after they take PALFORZIA to watch for allergic reactions.



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 children, symptoms occurring in a doctor's office generally started within a median time of 4 minutes of taking PALFORZIA and resolved after a median time of 37 minutes. Monitor your child for reactions and follow your child's 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 child's allergist's instructions, should any allergic reactions occur, be prepared to administer injectable epinephrine and seek medical attention immediately.

UP-DOSING AT A GLANCE

The Up-Dosing Phase typically lasts six months. Your child will move through 11 different dosing levels of PALFORZIA as tolerated.

The first dose of each Up-Dosing level is given in the allergist's office. If that dose level is tolerated, your child will continue to take that dose level every day at home for two weeks.



UP-DOSING CADENCE 6 MONTHS	
DOSE LEVEL	PALFORZIA DOSE
1	3 mg
2	6 mg
3	12 mg
4	20 mg
5	40 mg
6	80 mg
7	120 mg
8	160 mg
9	200 mg
10	240 mg
11	300 mg

The treatment process can be adapted to your child's unique needs at the discretion of your child's allergist. For example, your child's allergist may modify the dosing amount and/or schedule during Up-Dosing if your child experiences allergic reactions, needs to travel, or has an illness. Talk to your child's allergist if you have concerns about the dosing amount or schedule.

After completing the Up-Dosing Phase, your child will start taking a daily Maintenance Dose of 300 mg.

HELPFUL UP-DOSING TIPS

Here's what works for other PALFORZIA caregivers like you:



MAKE DOSING AND OBSERVATION FUN

"He would take a dose at 9 p.m., then he and his dad would stay up and watch a superhero movie... I think it made Luke feel special."
– Gretchen (caregiver of Luke, age 15)



TIMING THE ROUTINE

"Initially, I would wake her up early and give her PALFORZIA and monitor before she went to school. Now, because of her busy schedule, we're giving it to her in the evenings about an hour before bedtime. She likes that a little bit better."
– Misty (caregiver of Kendall, age 10)



DOSING CAN BE FLEXIBLE IF NECESSARY

"Maggie did have to maintain the same dose for longer than usual when she was sick. She stayed at the same level for one month rather than two weeks."*
– Katie (caregiver of Maggie, age 15)

*Dose modification is at the discretion of your child's allergist.

DO'S FOR TAKING PALFORZIA AT HOME



Continue to have your child carry their injectable epinephrine.



Have your 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 your 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 your child misses taking PALFORZIA, contact your child's allergist. Do not give 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 a menstrual period, exercising within a three-hour period after taking the dose, taking certain pain medications such as aspirin or ibuprofen, or drinking alcohol.

DON'TS FOR TAKING PALFORZIA AT HOME



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



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



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



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



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



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



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MAINTENANCE PHASE

THE MAINTENANCE PHASE

Taking PALFORZIA every day


Palförzia
Peanut (*Arachis hypogaea*)
Allergen Powder-dnfp

Please see additional Important Safety Information on pages 12–13, or full [Prescribing Information](#) and [Medication Guide](#), including an Important WARNING about anaphylaxis, at [PALFORZIA.com](#).



Congratulations on reaching the Maintenance Phase! Your child won't need to consume higher doses and can continue taking the same daily dose at home.

If IDE was your launchpad and Up-Dosing was your staircase, the Maintenance Phase is a consistent path for your family to follow into the future. With time, your child's PALFORZIA dose will eventually become a routine part of your family's life.



YOU MADE IT!

ONGOING MAINTENANCE DOSE	300 mg
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The Maintenance Phase continues over time to help your child maintain their decreased sensitivity to peanut allergens.

HOW THE MAINTENANCE PHASE WORKS

ONGOING DAILY DOSES

You will still be giving your child a dose of PALFORZIA every day at the same time, and you will still need to follow all the same mixing and dosing instructions. The biggest difference between the Maintenance Doses and those in the Up-Dosing Phase is that Maintenance Doses stay set at 300 mg, never getting any higher. They also come in small sachets, instead of capsules.

WATCHING FOR ALLERGIC REACTIONS

Because PALFORZIA treatment relies on intentional peanut protein 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 children, symptoms occurring in a doctor's office started within a median time of 4 minutes of taking PALFORZIA and resolved after a median time of 37 minutes. Monitor your child for reactions and follow your child's allergist's instructions.

Although uncommon, there is a risk of severe 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 child's allergist's instructions, should any allergic reactions occur, be prepared to administer injectable epinephrine and seek medical attention immediately.

LESS FREQUENT APPOINTMENTS

Since your child has reached the Maintenance Phase of treatment, your child will likely have fewer PALFORZIA-related appointments with your child's allergist. Talk to your child's allergist about what makes sense for your child going forward. Also tell your child's allergist about any allergic reactions your child experienced and if your child needs more epinephrine.



AVOID PEANUTS AND CARRY INJECTABLE EPINEPHRINE

Remember, PALFORZIA is not a cure. Your child must still avoid peanuts and always carry injectable epinephrine.



TIPS FOR REMEMBERING EVERY DOSE

As important as it is, keeping your child motivated to take PALFORZIA every day can be a challenge, especially as children get older and more independent. Helping them stay involved and responsible, and eventually giving them ownership of the process, should help them stick to their daily dosing schedule.

DO'S FOR THE MAINTENANCE PHASE



Continue to have your child carry their injectable epinephrine.



Have your 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 your 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 your child misses taking PALFORZIA, contact your child's allergist. Do not give 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 a menstrual period, exercising within a three-hour period after taking the dose, taking certain pain medications such as aspirin or ibuprofen, or drinking alcohol.

DON'TS FOR THE MAINTENANCE PHASE



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



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



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



Do not let your child inhale the powder.



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



TREATMENT AND DAILY LIFE

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TIPS FOR MAKING TREATMENT PART OF YOUR ROUTINE

Since PALFORZIA is going to be part of everyday life for your family, it is important to find ways to make that daily dose of medication fit into your routine as smoothly as possible.



TIMING

Taking PALFORZIA daily requires finding a time each day to administer treatment that works well for you and your child's schedules. When determining the best time to give PALFORZIA, there are some things that should be considered:

- **BECAUSE YOUR CHILD** will need to be monitored for at least an hour after taking treatment, find a time of day where most activities are finished and there's still time left for proper observation. For example, taking PALFORZIA with dinner works for some families; it's up to you to determine what works best for your family.
- **PALFORZIA SHOULD NOT** be given to a child who has been participating in a strenuous physical activity such as exercising, is feeling hot, has a fast heartbeat, or has taken a hot bath or shower. Wait to give PALFORZIA until after your child has cooled down and their heart is beating normally. Also, do not let your child participate in strenuous physical activity or take a hot bath or shower within 3 hours after taking PALFORZIA.

Whatever time you choose, make sure you can stick to it since PALFORZIA should be taken at the same time every day.

TRAVELING WITH PALFORZIA

Since PALFORZIA should be taken at the same time every day and must be refrigerated, you'll need to make arrangements to bring it with you when you're not at home.



Bring a copy of your PALFORZIA prescription as well as your prescribed injectable epinephrine.



If your trip overlaps with an allergist appointment, talk to your child's allergist about getting more of the same dose and extending the time between appointments.



Pack enough PALFORZIA for the whole time you will be gone, including a few extra doses in case your travel home gets delayed.



Keep your PALFORZIA stored in a cooler with ice or freezer gel packs, maintaining a temperature of 36°F–46°F (2°C–8°C) for the duration of the trip, and do not freeze.



Once you've reached your destination, keep your PALFORZIA in its original packaging in the refrigerator until use. If you are staying in a hotel, call ahead to make sure you get a room with a refrigerator.



Make sure your child is able to take their daily dose by packing enough soft food or getting soft food along the way that you can mix PALFORZIA into.



FOR YOUR COMMUNITY OF CAREGIVERS

As much as we would like to be with our children every moment of the day, this is not normally possible. There will inevitably be times during your child's PALFORZIA treatment when you will have to rely on friends, relatives, babysitters, teachers, and other caregivers for help. The following information can be given to these caregivers to help keep your child on track with the PALFORZIA treatment plan.

Remember, the following pages only cover how to give your child PALFORZIA—they are not a guide to managing peanut allergy in general. Please make sure that your secondary caregivers are well educated on your child's allergy and know how to administer injectable epinephrine before you trust them to administer PALFORZIA.



To obtain individual copies of the Secondary Caregiver information, visit www.PALFORZIA.com/caregivers to download and print copies from home.

QUICK CARE OVERVIEW

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

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.

Before giving the child PALFORZIA, please make sure you've discussed their allergy with their parent or guardian, making it clear that the child should maintain a strict peanut-free diet and ensuring that you know how to administer the prescribed injectable epinephrine.

HOW TO GIVE PALFORZIA

- **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.
- **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, such as yogurt, applesauce, or pudding, that's either cold or at room temperature (not hot) and 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.
- **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 immediately prior to or 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 children, symptoms occurring in a doctor's office generally started within a median time of 4 minutes of taking PALFORZIA and resolved after a median time of 37 minutes. Monitor the child for reactions and follow the child's 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 the child's allergist's instructions, should any allergic reactions occur, be prepared to administer injectable epinephrine and seek medical attention immediately.

DO'S FOR SECONDARY CAREGIVERS



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 yogurt, applesauce, 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 give 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 a menstrual period, exercising within a three-hour period after taking the dose, taking certain pain medications such as aspirin or ibuprofen, or drinking alcohol.

DON'TS FOR SECONDARY CAREGIVERS



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 give 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.



RESOURCES

WE ARE HERE TO HELP

Our commitment to providing families with support goes beyond just the treatment. Learn more about what to expect when getting started with PALFORZIA and additional helpful resources.



PALFORZIA PATHWAY™ SUPPORT PROGRAM

This program can help you understand your insurance coverage and financial assistance options for PALFORZIA.

Your child's allergist's office will assist in getting you enrolled in PALFORZIA Pathway. Ask your child's allergist how to get started in our program.



PALFORZIA PATHWAY™ CO-PAY SAVINGS PROGRAM

With this program, eligible commercially insured patients may pay as little as \$20 per month out of pocket for PALFORZIA.

Patients may be eligible if they:

- Are taking PALFORZIA for an FDA-approved use
- Have commercial health insurance, including insurance purchased through state and federal health insurance exchanges
- Have PALFORZIA coverage through their health plan
- Are not enrolled in a government-sponsored health insurance program, including but not limited to Medicaid, Managed Medicaid, TriCare, and Medicare

For more information, visit www.PALFORZIACoPay.com.



PALFORZIA PATHWAY™ PATIENT ASSISTANCE PROGRAM

This program provides PALFORZIA at no cost to eligible patients.

If you have no insurance, or if your insurance has denied coverage for PALFORZIA and you meet certain financial eligibility criteria, you may be eligible to receive PALFORZIA at no cost to you.

Eligibility for the program requires a valid, on-label prescription. For more information, call 1-844-PAL-FORZ (1-844-725-3679) and select option 2.





LEARN MORE ONLINE

Visit PALFORZIA.com to learn more.

For REMS information, visit PALFORZIAREMS.com.
Your child's allergist will help you enroll in the
PALFORZIA REMS program.



GET IN TOUCH WITH US

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

**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.**

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