

PALFORZIA® and your child

Important safety information
for PALFORZIA®▼
(defatted powder of *Arachis
hypogaea L.*, semen (peanuts))

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Caregiver safety educational booklet



Indication:

PALFORZIA contains peanut protein from defatted powder of peanut seed. It is a treatment for people who are allergic to peanuts (*Arachis hypogaea L.*).

PALFORZIA is intended for children and adolescents aged 4 through 17 years and those who become adults whilst on treatment.

PALFORZIA works in people with peanut allergy by gradually increasing the body's ability to tolerate small amounts of peanut; this is known as "desensitisation". PALFORZIA can help reduce the severity of allergic reactions after exposure to peanut.

PALFORZIA is not effective against any other nut or food allergies.

Patients who are taking PALFORZIA should continue to avoid eating peanuts.

Reporting side effects

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get to their doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

<https://www.hpra.ie>

By reporting side effects, you can help provide more information of the safety of this medicine.

About this booklet

Now that your child has been prescribed PALFORZIA, this booklet aims to provide important safety information about PALFORZIA treatment. It should be read alongside the patient information leaflet contained in your child's pack of PALFORZIA.

Booklets and videos for children

There is a series of age-appropriate booklets available for your child

There is also a handbook for caregivers and a series of videos for your child to watch that follow the story in this booklet, which you can access by going to:

www.medicines.ie

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Summary of safety information

Summary of safety information

Please ensure that you read and understand the following information and have explained it to your child – if you have any questions, don't hesitate to ask your doctor.

PALFORZIA is a medicine for peanut allergy and, like all medicines, it can have side effects.

This booklet contains important information about how to take the medicine safely, but before we get into that, we need to explain two potential side effects that can occur with PALFORZIA: **Anaphylaxis and Eosinophilic oesophagitis (EoE)**.

To minimise the risk of a reaction, it is important that you and your child know:

- Symptoms to watch out for
- When to contact your doctor or emergency services
- The important Do's and Don'ts of treatment

Anaphylaxis

Anaphylaxis is a type of allergic reaction that may affect different parts of the body at the same time. It can range from mild to severe and it can be life-threatening. Reactions can happen immediately or a few hours after coming into contact with an allergen (a substance that causes an allergy). Anaphylaxis can include a combination of the following symptoms:

- Trouble breathing
- Throat tightness or feeling of fullness in the throat
- Trouble swallowing or speaking
- Changes in the voice
- Dizziness or fainting or feeling of impending doom
- Severe stomach cramps or pain, vomiting, or diarrhoea
- Severe flushing or itching of the skin

If your child experiences any combination of these symptoms and you suspect anaphylaxis, follow your child's emergency anaphylaxis plan, use your child's adrenaline autoinjectors following the instructions on the devices and call emergency services.

If you or your child have questions or concerns about using your child's adrenaline autoinjectors talk to your doctor who can explain how and when to use the devices.

Eosinophilic oesophagitis

Eosinophilic oesophagitis (EoE) is a disease where a type of white blood cells (called eosinophils) build up in the tube that connects the mouth to the stomach (oesophagus).

It has been reported by some people with peanut allergy receiving oral immunotherapy.

Symptoms of eosinophilic oesophagitis can include:

- Trouble swallowing
- Food stuck in throat
- Burning in chest, mouth, or throat
- Regurgitation
- Loss of appetite

If your child experiences any of these symptoms, please contact your doctor who will carefully monitor your child for stomach problems. If they suspect EoE, the PALFORZIA treatment will be stopped.

Other possible side effects:

Throat tightness, vomiting, stomach discomfort or ache, feeling sick, allergic reactions (mild, moderate or severe), cough, sneezing, throat irritation, tingling of mouth or itching in and around the mouth, hives, itchy skin, difficulty breathing, wheezing.

Dos and Don'ts

To minimise your child's risk of side effects, please make sure they stick to the following Do's and Don'ts of PALFORZIA treatment.

✓ Dos



Take their PALFORZIA every day



Take their PALFORZIA with food



Take their PALFORZIA at roughly the same time of day (with their evening meal is best)



Carry their adrenaline autoinjectors with them at all times

X Don'ts



DO NOT eat peanuts



DO NOT drink alcohol 2 hours before or after taking a dose



DO NOT take their PALFORZIA if they feel sick



DO NOT exercise, or take a hot shower or bath right before or for 3 hours after taking their PALFORZIA



DO NOT take their PALFORZIA within 2 hours of bedtime



DO NOT swallow the capsule or breathe in the powder

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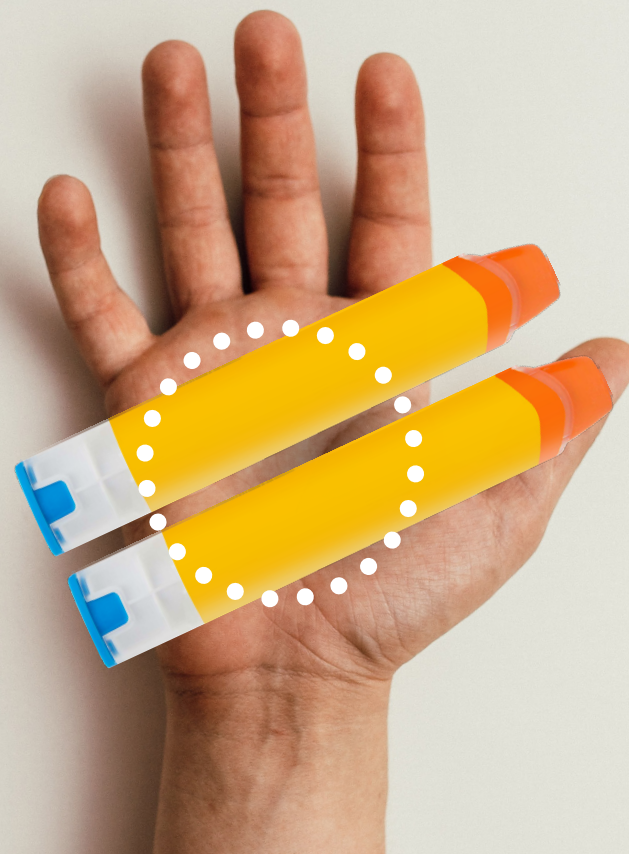
Some key things to remember



Your child should still **never eat peanuts, or food that contains peanuts**, even after taking PALFORZIA.



Your child should **always** carry their adrenaline autoinjectors with them.





Your child must take their medicine **every day, with food, at roughly the same time each day.**

With their evening meal is best.



Your child must not swallow the capsule(s). Capsules and sachets should be opened and the powder mixed into food, that your child isn't allergic to and can't be hot or too watery.

✓ Good foods to do this with include rice-pudding, fruit puree, or yoghurt.

✗ Foods you shouldn't mix it into include soup and smoothies.






Some key things to remember



Make sure your child **hasn't been running around or doing exercise** right before or for 3 hours after taking PALFORZIA.



Your child **should not** take PALFORZIA if they feel unwell.



Your child **should not** take a hot bath or shower right before or for 3 hours after taking PALFORZIA.



Your child **should not** take **PALFORZIA** within 2 hours of going to sleep.

A hand holding a glass of beer. The glass is filled with a golden beer topped with a thick white head of foam. The hand is positioned in the lower left, gripping the stem of the glass. The background is a plain, light-colored surface.

Some key things to remember



Alcohol can change the way the body reacts to PALFORZIA.

Make sure to talk to your child about this. If they do drink alcohol, it should not be 2 hours before or after taking a dose.



Menstruation can change the way the body reacts to PALFORZIA.

If your child has symptoms while they are menstruating, make sure to tell your doctor who may change their dose of PALFORZIA.





Non-steroidal anti-inflammatory medicines (such as ibuprofen) can change the way the body reacts to PALFORZIA.

Use extra caution when giving these medicines to your child.



Consider contacting your child's doctor if any of the following applies:

- **Your child develops an intercurrent illness (such as a cold or the flu)**
- **Your child's asthma gets worse**
- **Your child is highly stressed**
- **Your child is unusually tired or can't sleep for several days**



About PALFORZIA

About PALFORZIA

Below are some answers to questions you may have about your child's PALFORZIA treatment:

What is PALFORZIA and who can take it?

PALFORZIA is an oral immunotherapy medicine for treating peanut allergy. It is a medicine for children and teenagers, aged 4 to 17 years, who have been diagnosed with peanut allergy. If your child started taking PALFORZIA before they turn 18 they can continue taking it after their 18th birthday.

PALFORZIA is a powder that contains a small and very precisely measured amount of peanut proteins. This medicine is given in small doses that are mixed with food and eaten. The doses are slowly increased over several weeks.

Who can't take PALFORZIA?

People who should never take PALFORZIA are those who have:

- Severe or uncontrolled asthma.
- Have or have had problem swallowing or long term problems with your digestive system including eosinophilic oesophagitis (EoE) and gastroesophageal reflux disease (GERD)
- A history of or current severe mast cell disorder.
- Hypersensitivity to any of the inactive ingredients used to make PALFORZIA. (microcrystalline cellulose, partially pre-gelatinised maize starch, colloidal anhydrous silica, magnesium stearate).
- Severe or life-threatening anaphylaxis within 60 days before starting treatment with PALFORZIA.

If you are unsure about or have never heard of any of these conditions then speak to your doctor and they will be able to explain more about them.

How long should my child take PALFORZIA for?

Taking PALFORZIA daily is required to maintain the effects and tolerability.

Currently, data are available for up to 24 months of treatment with PALFORZIA.

Is my child still allergic to peanut while taking PALFORZIA?

Yes, they are still allergic to peanut, even if they might not have an allergic reaction if they eat a peanut by accident. PALFORZIA aims to desensitise your child's immune system to peanut, but it isn't a cure for peanut allergy. It is vital that they keep taking PALFORZIA every day to maintain the desensitisation.

Taking PALFORZIA

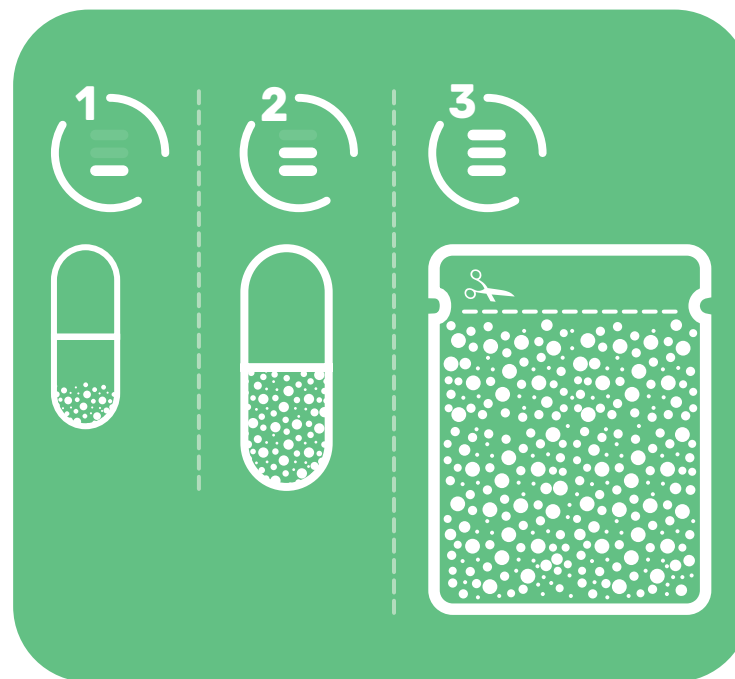
? How and when should my child take PALFORZIA?

- Your child will need to take PALFORZIA every day, at roughly the same time each day. With their evening meal is best.
- They must not swallow the capsule or inhale the powder. Capsules and sachets should be opened and the powder should be emptied and mixed into food, which can't be hot or too watery.
- Use a small amount of a food that your child likes and that can be eaten easily in one sitting. Good foods to do this with include rice-pudding, fruit puree or yoghurt.
- Foods you shouldn't mix it into include milk, soup and smoothies.
- Your child should still strictly avoid peanuts, or food that contains peanuts.
- They should always carry their adrenaline autoinjectors.
- Make sure that your child hasn't been running around or doing exercise right before, or for 3 hours after, they take their PALFORZIA.
- Make sure that your child doesn't have a hot bath or shower right before, or for 3 hours after, they take their PALFORZIA.
- They should wait at least two hours after eating PALFORZIA before they go to sleep.

Remember: your child must not swallow the capsules. Capsules should be opened, emptied into food and mixed thoroughly.

The three phases of treatment

Once your doctor has decided that it is okay for your child to start taking PALFORZIA, they will start the first of three dosing phases. This is so that they can gradually increase the amount of medicine your child takes over time. For phase 1, your child will receive their PALFORZIA in capsules. For phase 2, PALFORZIA will come in capsules until the last dose level which will come in a sachet. For phase 3, they will receive their PALFORZIA in a sachet. At all phases, the PALFORZIA should be emptied from the capsules or sachets and mixed into food for your child to eat.



Phase 1 Initial Dose Escalation (2 days)

When your child first starts taking PALFORZIA, you will go to see the doctor for 2 days in a row.

Day 1 - Approximate total time in doctor's clinic: 4-5 hours

- If your child is well enough to start treatment, they will receive 1 dose of PALFORZIA in the clinic under medical supervision **every 30 minutes** until they have taken **5 doses**.
- The doses start off very small at 0.5 mg and slowly get bigger to 6 mg. After they have taken each dose, the doctor will check to see that they are feeling well.
- If any symptoms that require medical intervention (e.g. using adrenaline) happen during this phase, treatment will be stopped.
- After dose number 5 has been taken, you and your child will need to stay at the clinic for at least 60 minutes so the doctor can make sure they're well.
- If your child can tolerate dose number 4 but not dose number 5, they can continue with treatment but will have to come back to the doctor's clinic before starting phase 2 (Up-dosing) of treatment.

Day 2 - Approximate total time in doctor's clinic: 2 hours

- If your child tolerated the doses on Day 1, you will come back to the doctor's clinic on Day 2.
- The doctors and nurses will perform a few health checks and ask how your child felt when they got home yesterday. If they feel okay and their tests have come back with good results then the doctor will give them one 3 mg dose of PALFORZIA and check that they are okay.
- If this dose is tolerated, you and your child will go home with 2 weeks' worth of 3 mg doses of PALFORZIA.
- For the next 2 weeks, your child should take PALFORZIA at home, once a day with food.

When taking PALFORZIA at home, you and you child must remember to follow the instructions on page 22. And if they feel unwell or have an allergic reaction at any point, then make sure that they tell you and you use your child's adrenaline autoinjectors and contact emergency services if necessary. You can speak to your doctor if you have any concerns.

Remember:



Do not give your child a dose of PALFORZIA at home on days where you're going to the doctor's clinic for a new dose.



Your child still needs to take PALFORZIA **every day** for it to work properly.



They must still be very careful **not to eat peanuts** and food with peanuts.



They must still always have their **adrenaline autoinjectors** with them.

PALFORZIA and your child

Taking PALFORZIA

Phase 2: Up-dosing period (approx. 6 months)

- After 2 weeks, you and your child will go back to the doctors to see if they're ready for a new, slightly larger dose of PALFORZIA.
- **Your child should not take their dose of PALFORZIA at home on the days that they go to the doctors.**
- If everything is going well with your child's treatment, the doctor will give your child a new higher strength dose and observe them for at least 60 minutes before you can take them home.
- At home, they'll need to take PALFORZIA at roughly the same time every day. After two weeks, they'll go back to the doctors and, if everything is going well, they'll be given a new, slightly higher strength dose.
- They'll repeat this process of taking their daily dose at home and heading back to the doctors for about 6 months as their dose of PALFORZIA is increased from 3 mg to 300 mg a day over 11 dose levels.
- If your child missed any doses, had an illness, side effects or allergic reactions, or they are about to go through a particularly stressful time (e.g. exams), your doctor may decide to keep your child at the same dose, or reduce the dose, and check to see how they are doing in another 2 weeks. This will allow their body to become more 'used' to the dose level. Your doctor will explain this to you and your child if this happens.
- Your doctor will make sure that your child has the right dose of PALFORZIA to take every day at home until your next visit.

0.5 mg



1 mg



10 mg



20 mg



100 mg



300 mg



Children should be given each dose of PALFORZIA **by an adult and they should be watched for about 1 hour** afterwards for any symptoms of an allergic reaction.

Phase 3 Maintenance

- Once your child can take the 300 mg daily Maintenance dose safely, they have reached phase 3.
- **As before, your child shouldn't take their usual dose of PALFORZIA at home on the day that they visit the doctor.**
- You and your child will be given a box containing 1 month's supply of 300 mg sachets of PALFORZIA to take home. See the next page for instructions of how to mix the PALFORZIA with food.
- During the Maintenance phase of treatment, your child's doctor will confirm how often they will need to go for a check-up appointment.

300 mg



Remember:



Your child still needs to take PALFORZIA every day for it to work properly.



Watch your child for about 1 hour after they take their dose to check for any symptoms of an allergic reaction



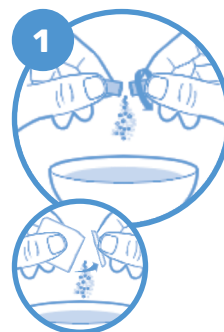
Your child must still be very careful not to eat peanuts and food with peanuts.



Your child must still always have their adrenaline autoinjectors with them.

Mixing PALFORZIA with food

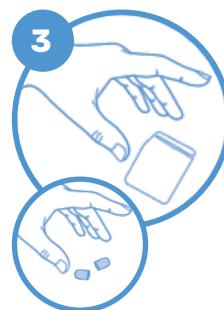
- PALFORZIA will come in a capsule(s) or sachet, depending on the dose level (capsule(s) up to 240 mg, and a sachet for 300 mg). Each capsule or sachet contains PALFORZIA (a powder) that you or your child will mix with a small amount of food that your child isn't allergic to.
- Make sure you don't mix the PALFORZIA with too much food, so that your child can easily eat the whole dose in a few spoonfuls, and don't heat the food.
- During phase 2 (Up-dosing) your child's pack of PALFORZIA is divided into daily doses which may be made up of one or several individual capsules. During phase 3 (Maintenance dosing), your child's pack of PALFORZIA is divided into daily doses which are individual 300 mg sachets.



- Empty the entire contents of the capsule(s) or sachet into a dish containing a small amount of a soft food that isn't hot or too liquid (yoghurt, rice-pudding or fruit puree are good examples).
- If using one or several capsules, twist them open over a bowl of food and pour the powder into the food. If using a sachet, hold it over the food and cut across the top of the sachet with a pair of scissors then empty the contents of the sachet into the food.



- Stir the powder into the food until it is completely mixed in with no lumps.



- Throw the empty sachet or capsule(s) away into a rubbish bin.



- Please make sure that your child eats all of the food you mixed their dose of PALFORZIA into.



- If, for any reason, you can't prepare a new PALFORZIA/food mixture, it can be stored for up to eight hours in the fridge.
- If they don't eat the dose within eight hours of preparation, throw it away and make a new mixture.



- Please wash your hands immediately after handling the PALFORZIA capsules or sachets.

? What if my child misses a dose of PALFORZIA?

Do not take a double dose to make up for a forgotten dose.

If your child misses one or two days of PALFORZIA, make sure that they take the next dose, at the usual time, the following day.

If they miss **three or more days** of PALFORZIA, you should contact your doctor **before they take the next dose**.

Your child may have to go back to the doctors and take PALFORZIA in front of them if they haven't taken it for a few days. The doctor will check to see that your child is healthy and that everything is okay.

Understanding PALFORZIA doses

PALFORZIA dosing phase 2 (Up-dosing) is broken into 11 steps. At each step, the daily dose of PALFORZIA is slightly increased. For the first 10 steps, the doses come in capsules of different shapes, sizes and colours which are grouped together in separate blisters. At the 11th step, and during Maintenance dosing, the daily dose comes in a sachet. This is what the capsules and sachet will look like at each Up-dosing step.

It is important to keep a record of the batch number of your PALFORZIA. So, every time you get a new package of PALFORZIA, note down the date and the batch number (which is on the packaging after "Lot") and keep this information in a safe place.

Step 1

(3 mg daily dose)



Step 2

(6 mg daily dose)



Step 3

(12 mg daily dose)



Step 4

(20 mg daily dose)



Step 5

(40 mg daily dose)



Step 9

(200 mg daily dose)



Step 6

(80 mg daily dose)



Step 10

(240 mg daily dose)



Step 7

(120 mg daily dose)



Step 11

(300 mg daily dose)



Step 8

(160 mg daily dose)



4

Other practical information

Other practical information

? Where should we store PALFORZIA?

You should keep PALFORZIA in an area of your home with a room temperature that is no higher than 25°C and that is out of reach of children. This means you should store it in a place in your house that has a moderate room temperature, away from direct sunlight. A cool, dark cupboard may be best.

? How should my child use their patient card?

Patient Card	
Name	Phone
Address	Date of Birth
Emergency contact (Name)	Phone
Emergency contact (Address)	Phone

Your child will be given a patient card that tells people that they are taking PALFORZIA. You or your child should write their information on this card and make sure that they show it to a doctor, nurse or paramedic if they have to go to the doctors or to the hospital.

? Pregnancy and PALFORZIA?

No one should start taking PALFORZIA if they are pregnant or planning to become pregnant. If someone is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, they must ask their doctor for advice before taking this medicine.

? Menstruation and PALFORZIA?

Menstruation can change the way the body reacts to PALFORZIA and can make allergic symptoms more likely.

? Alcohol and PALFORZIA?

Drinking alcohol may increase the likelihood of an allergic reaction after taking PALFORZIA.

? Unused doses

When your doctor has told you that your child's Updosing level is complete, you must throw away any remaining doses (capsules or sachets) from that pack before starting a new dose level. This includes any extra doses that are provided in each pack that they haven't used.



Contact information

Aimmune Therapeutics Ireland Ltd.
Block B
The Crescent Building
Northwood, Santry, Dublin 9
Dublin
D09 C6X8
Republic of Ireland

Phone: +353 1 893 4957

Email: info.ie@aimmune.com

Medical information and safety reporting

Email: medinfo-eu@aimmune.com

Tel: +353 (0) 15827964

