

PALFORZIA® and you

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.

**Patient safety
educational booklet**

Ages 12-17 years



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.

PALFORZIA treatment: A Guide for Teenagers

If you are a teenager with peanut allergy who has been prescribed PALFORZIA, then this guide is for you. It aims to answer your questions about your PALFORZIA treatment.

This booklet gives you information about:

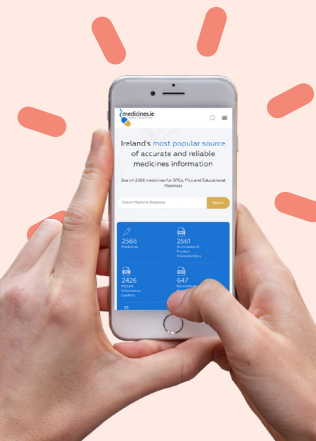
- What PALFORZIA is and who can and can't take it
- How and when to take PALFORZIA
- Side effects you might experience after taking PALFORZIA, and what to do if you do experience any
- Other important safety information when taking PALFORZIA

Booklets and videos

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

Although we have tried to cover everything that you might need to know about PALFORZIA, don't be afraid to ask your doctor for more information on anything in this booklet. More information can also be found in the package leaflet contained within your pack of PALFORZIA.



Contents

Page 7 **Section 1:** Some key things to remember

Page 14 **Section 2:** About PALFORZIA

Page 16 **Section 3:** Possible side effects of PALFORZIA

Page 18 **Section 4:** Taking PALFORZIA

Page 26 **Section 5:** Other practical information

Summary of safety information

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

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

This booklet contains important information about how to safely take the medicine, 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 know:

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

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

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

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 you experience any of these symptoms, please contact your doctor who will carefully monitor you for stomach problems. If your doctor suspects 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 risk of side effects, please make sure you stick to the following Do's and Don'ts of PALFORZIA treatment.

✓ Dos



Take your PALFORZIA every day



Take your PALFORZIA with food



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



Carry your adrenaline autoinjectors with you 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 your PALFORZIA if you feel sick



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



DO NOT take your PALFORZIA within 2 hours of bedtime



DO NOT swallow the capsule or breathe in the powder

1

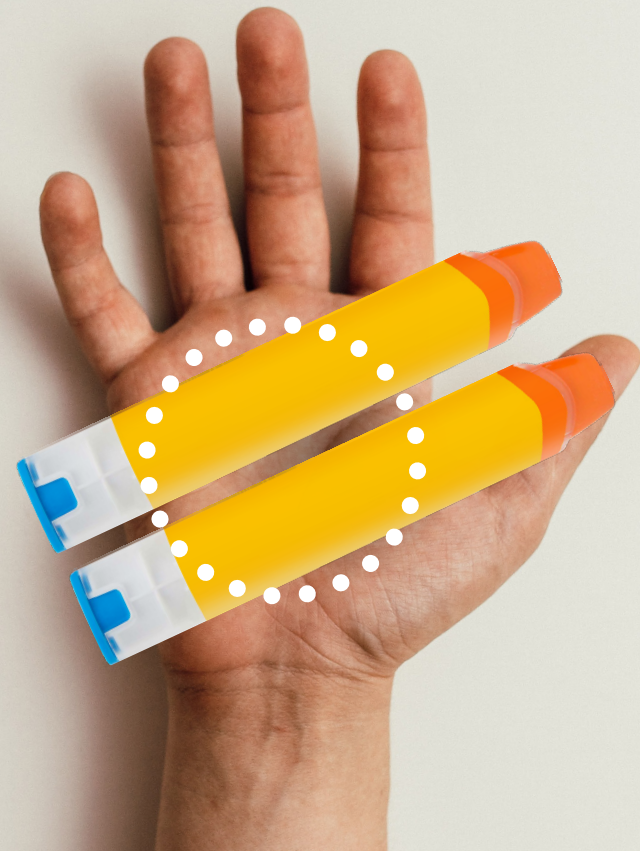
Some key things to remember



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



You should **always** carry your adrenaline autoinjectors with you.





You must take your medicine **every day, with food, at roughly the same time each day.**

With your evening meal is best.



You must not swallow the capsule(s). Capsules and sachets should be opened and the powder mixed into food that you aren't allergic to, which 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.





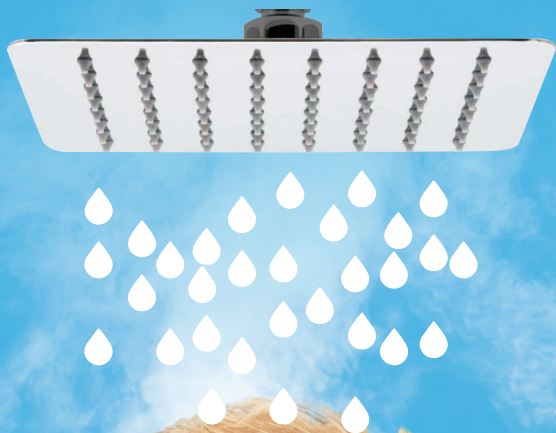
Make sure you haven't **been running around or doing exercise** right before or for 3 hours after taking PALFORZIA.



You **should not** take PALFORZIA if you feel unwell.

X

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



X

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



Do not drink alcohol
2 hours before or
after taking a dose.



Menstruation can change
the way the body reacts to
PALFORZIA.

**If you are menstruating and experience
any allergic symptoms, make sure to tell
your doctor who may change your dose
of PALFORZIA.**





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

Use extra caution if you take these medicines.



Consider contacting your doctor if any of the following applies:

- **You get a cold or flu**
- **Your asthma gets worse**
- **You feel highly stressed**
- **You are unusually tired or have bad sleep for several days**

2

About PALFORZIA

? 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 esophagitis (EoE) and gastroesophageal reflux disease (GERD).
- Have a history of or current severe mast cell disorder.
- Have hypersensitivity to any of the inactive ingredients used to make PALFORZIA. (Microcrystalline cellulose, partially pre-gelatinised maize starch, colloidal anhydrous silica, magnesium stearate).
- Have 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.

? Am I still allergic to peanut while taking PALFORZIA?

Yes, you are still allergic to peanut, even if you might not have an allergic reaction if you eat a peanut by accident. PALFORZIA aims to desensitise your immune system to peanut, but it isn't a cure for peanut allergy.

It is very important that you keep taking PALFORZIA every day to maintain the desensitisation and that you continue to avoid peanuts and carry your adrenaline autoinjectors.

? How long should I 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.



Remember:

You should still never eat peanuts, even after taking PALFORZIA.

3

Possible side effects of PALFORZIA

Side effects with PALFORZIA

Like all medicines, PALFORZIA can cause side effects, although not everybody gets them.

This is because PALFORZIA relies on intentional peanut protein exposure. Based on evidence from PALFORZIA clinical trials, allergic reactions should be expected, but most should be mild or moderate and happen less often with time.

Important side effects include:

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

Your doctor will talk to you and your parent or caregiver more about these symptoms to help you look out for them and know the steps to take if you have them. You should let the doctor know if you experience any of these symptoms.

Anaphylaxis

PALFORZIA can cause severe allergic reactions that may be life-threatening. Symptoms of allergic reactions to PALFORZIA can include:

- Trouble breathing
- Throat tightness or swelling
- Trouble swallowing or speaking
- Dizziness or fainting
- Severe stomach cramps or pain, vomiting, or diarrhoea
- Severe flushing or itching of the skin

If you experience any of these symptoms, stop PALFORZIA, treat the reaction according to any instructions previously provided by your doctor and then contact a doctor **immediately**. These reactions might happen right after you take the drug, or up to a few hours later.

Eosinophilic oesophagitis

PALFORZIA can cause gastrointestinal symptoms including a problem with the food pipe, called eosinophilic oesophagitis. Symptoms of eosinophilic oesophagitis can include:

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

If you experience these symptoms persistently, contact a doctor.

Use your adrenaline autoinjectors and seek medical treatment straight away if you have any of the following symptoms:

- **Trouble breathing**
- **Throat tightness or swelling**
- **Trouble swallowing**
- **Change in voice**
- **Dizziness or fainting or feeling of impending doom**
- **Severe stomach cramps or pain, vomiting or diarrhoea**
- **Severe flushing or itching of the skin**
- **Worsening of asthma or any other breathing condition that gets worse**
- **Heartburn, difficulty swallowing, pain with swallowing, or severe chest pain that does not go away or gets worse**

Your doctor will talk to you and your parent or carer about how to look out for these symptoms and what to do if they happen.

4 Taking PALFORZIA

The three phases of treatment

Once your doctor has decided that it is okay for you to start taking PALFORZIA, they will start the first of 3 dosing phases. This is so that they can gradually increase the amount of medicine you take over time. There may be times when you have to stay on the same dose for longer, reduce your dose or stop dosing altogether. Your doctor will be able to advise you on when this might be.

For phase 1, you will receive your 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, you will receive your PALFORZIA in a sachet. At all phases, the PALFORZIA should be emptied from the capsules or sachets and mixed into food for you to eat.



≡ Phase 1 (2 days)

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

Day 1

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

Day 2

- 1.** The doctor will perform a few health checks and ask how you felt when you got home yesterday. If you feel okay and your tests have come back with good results then the doctor will give you 1 dose of PALFORZIA and check that you are okay.
- 2.** If this dose is tolerated, you will go home with a 2-week supply of this dose of PALFORZIA.
- 3.** For the next 2 weeks, you should take PALFORZIA at home, once a day with food.

Remember: When you take PALFORZIA at home, you must follow the instructions (on page 22). If you feel unwell or have an allergic reaction at any point, then please tell your parents and/or doctor.

≡ Phase 2 (about 6 months)

- After 2 weeks, you will go back to the doctors clinic for a new, slightly larger dose of PALFORZIA.
- **You should not take your dose of PALFORZIA at home on the days that you go to the doctors.**
- If everything is going well with your treatment, the doctor will give you a new higher strength dose and you'll stay at the clinic for at least 60 minutes before you can go home.
- At home, you'll need to take PALFORZIA at roughly the same time every day. After 2 weeks, you'll go back to the doctors and, if everything is going well, you'll be given a new, slightly higher dose.
- You'll repeat this process of taking your daily dose at home and heading back to the doctors for about 6 months as your dose of PALFORZIA is increased from 3 mg (roughly 1% of the protein in a peanut kernel) to 300 mg (roughly the same amount of protein as one peanut kernel) a day over 11 dose levels.
- There may be times when your doctor will

prescribe a smaller dose or keep you on the same dose for longer if you experience side effects. This will allow your body to become 'used' to the dose level. Your doctor will explain this to you if this happens.

- Your doctor will make sure that you have the right dose of PALFORZIA to take every day at home until your next visit.



≡ Phase 3

- Once you can take the 300 mg daily dose safely, you have reached stage 3. This is the Maintenance phase.
- **As before, don't take your usual dose of PALFORZIA at home on the day that you visit the doctor.**
- You will be given a box containing one month's supply of 300 mg sachets of PALFORZIA to take home. **See page 22** for instructions of how to mix the PALFORZIA with your food.
- During the Maintenance phase of treatment, your doctor will confirm how often you will need to go for a check-up appointment

300 mg



Remember:



- **You still need to take PALFORZIA every day for it to work properly.**



- **Be extra cautious for about 1 hour after you have taken your dose and make sure that an adult is around to help you in case of symptoms of allergic reaction.**



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



- **You must still always have your adrenaline autoinjectors with you.**

Mixing PALFORZIA with your food

- 1 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 a powder that you or your parent will mix with a small amount of soft food that you aren't allergic to and that isn't hot or too liquid (yoghurt, rice-pudding or fruit puree are good examples).
- 2 Make sure you don't mix PALFORZIA with too much food, so that you can eat the whole dose in a few spoonfuls, and don't heat the food.
- 3 Remove your total daily dose from your pack of PALFORZIA. When using capsules, your daily dose will be stored in an individual blister in your pack and can be made up of one capsule or several capsules depending on your dose. When using the sachets, one sachet is the total daily dose.
- 4 If using capsule(s), twist every capsule open over your food. If using a sachet, hold it over the food and cut across the top of the sachet with a pair of scissors.
- 5 Empty the entire contents of the capsule(s) or sachet into the dish containing the food.

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

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

8 Please make sure that you eat the full amount of each daily dose.

9 Doses of PALFORZIA and food mixture can be prepared and stored in the fridge for up to 8 hours.

10 If you don't eat the dose within 8 hours of preparation, throw it away and make a new mixture.

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

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, you or your parent/caregiver should 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)



5

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. 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 I use the PALFORZIA patient card?

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

The image shows a 'Patient Card' for PALFORZIA. It includes fields for Name, Address, Emergency contact (Name and Phone), and Allergies. Below the form is a red box with important instructions in small text.

What will happen with any other allergic diseases I have (e.g. asthma, hay fever, eczema, allergies to other foods)?

The other allergies still need to be well taken care of. If you use medicine for these allergies (inhalers, creams or pills), you must keep on using them.

Your parent or caregiver will decide whether it might be best for you to miss the PALFORZIA.

dose for the day and see how you feel the next day. You or your parent or caregiver should contact your doctor if you have any questions.

Pregnancy and PALFORZIA

Don't start taking PALFORZIA if you are pregnant or planning to become pregnant. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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 an Up-dosing 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 you 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

