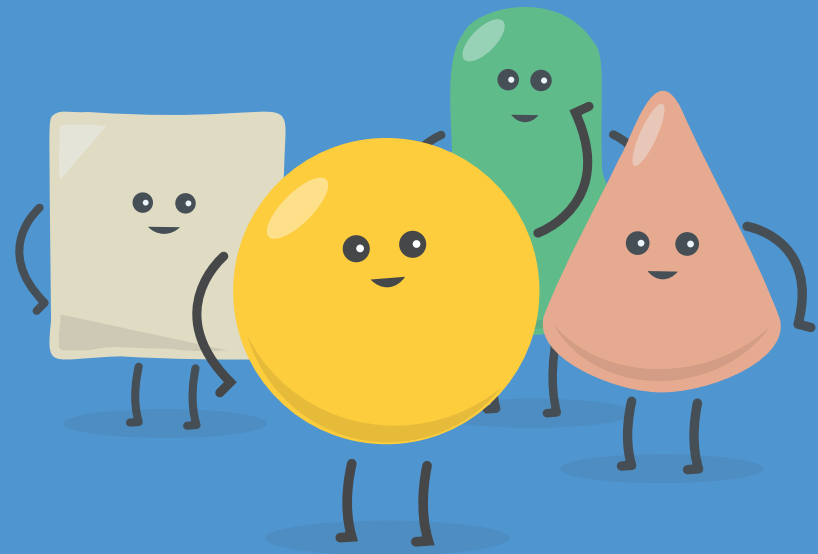


# PALFORZIA® and you

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 7-11 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.

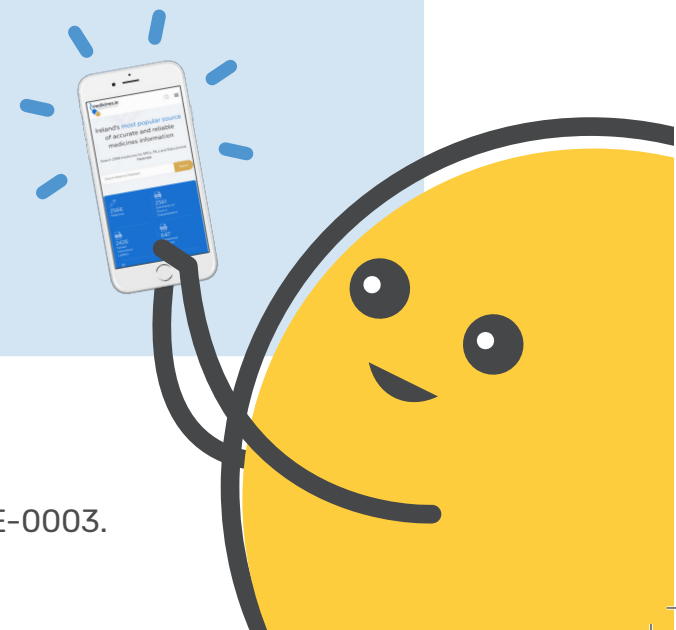
# For Caregivers: About this booklet

Now that your child has been prescribed PALFORZIA, this booklet aims to give you and your child 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

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](http://www.medicines.ie)**



## Note for caregivers

### 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 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 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** 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 (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 your child sticks to the following Do's and Don'ts of PALFORZIA treatment.

## ✓ Dos



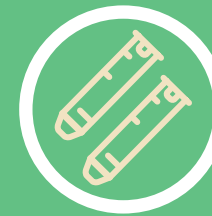
Take your  
PALFORZIA  
every day



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 take  
your PALFORZIA  
if you feel sick



DO NOT take  
your PALFORZIA  
within 2 hours  
of bedtime



DO NOT swallow  
the capsule or  
breathe in the  
powder



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



### Note for caregivers

Summary of safety information

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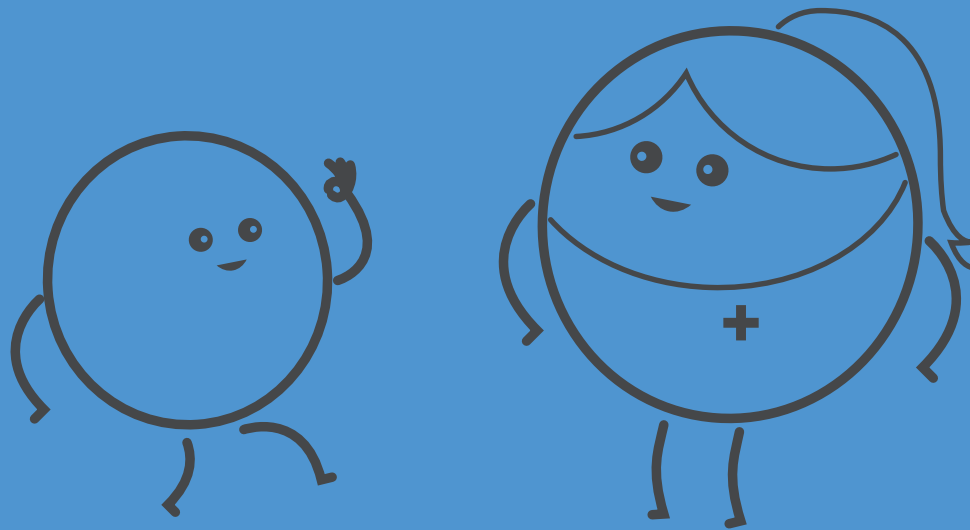
**Page 20** **Section 3:** Arlo takes PALFORZIA for the first time

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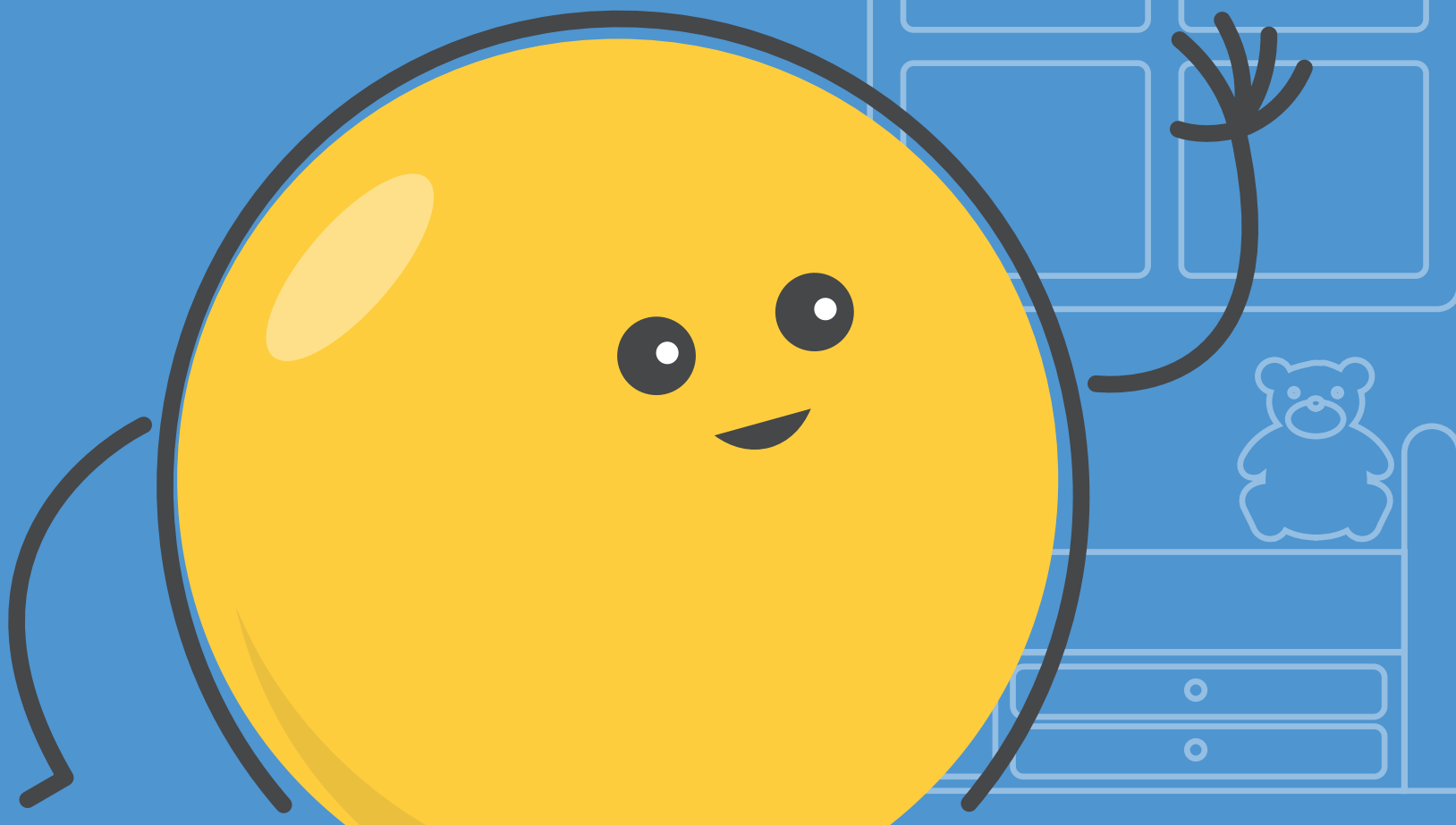
**Page 26** **Section 5:** Arlo gets a tummy ache

1

# Arlo and PALFORZIA




**This is Arlo! He has a peanut allergy and his doctor has prescribed him a medicine called PALFORZIA.**





**One day, Arlo went to the doctors  
to learn about important safety  
information for PALFORZIA.**





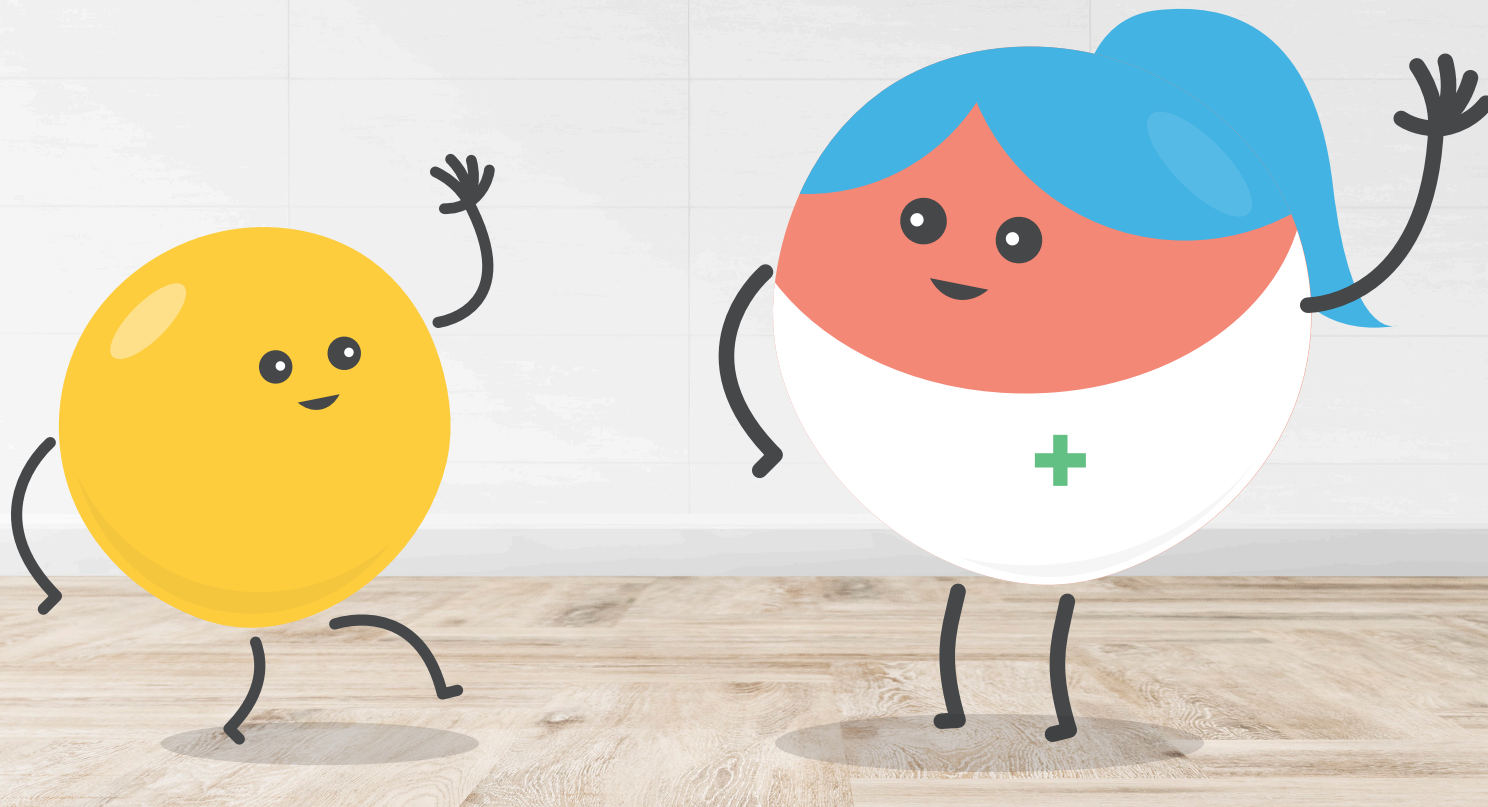
**“Hi doctor,” said Arlo. “I have a peanut allergy and have been prescribed PALFORZIA. What important information do I need to know about?”**

**“Hello Arlo,” replied the doctor.**

**“When you are taking PALFORZIA, you should still never eat peanuts.”**


**“Before you can start taking PALFORZIA, I need to check that you are healthy and don’t have a high temperature. And I’m also going to do a couple of quick tests.”**

**“Okay!” replied Arlo.**



The doctor carried out a test on Arlo to check how well his lungs were working, and measured his temperature.






The doctor was happy with the test results which meant that he was okay to start taking PALFORZIA.

“Come back next week and I will show you how to take the medicine,” said the doctor. “But before you go, do you have any questions?”



Arlo did have a couple of questions.



“Am I still allergic to peanuts, even when I take PALFORZIA?”

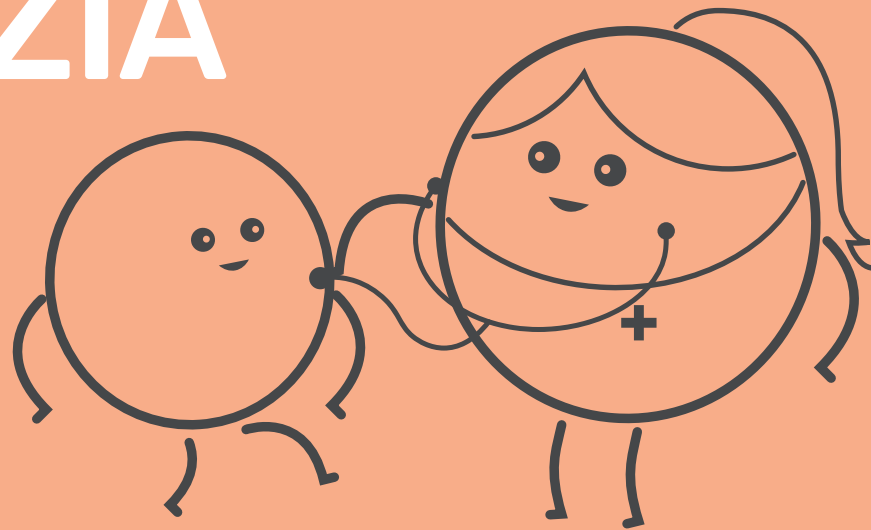



“Yes,” replied the doctor. “But if you keep taking the medicine then you will be less likely to become unwell if you eat peanuts. You still need to avoid them and carry your adrenaline autoinjectors just in case you need them.”



2

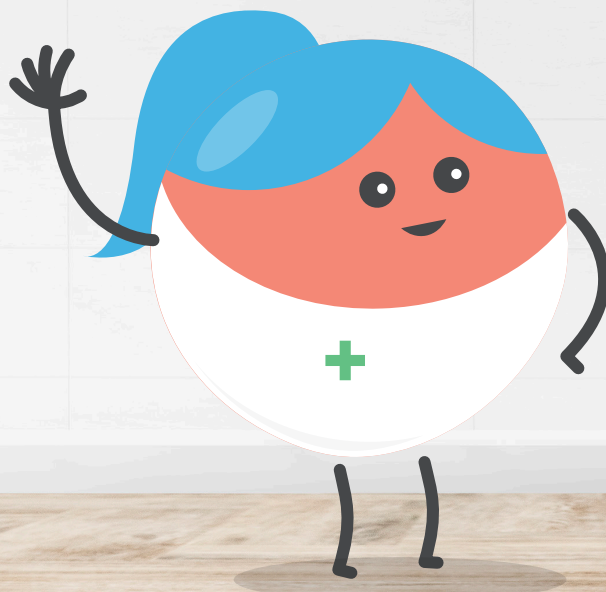
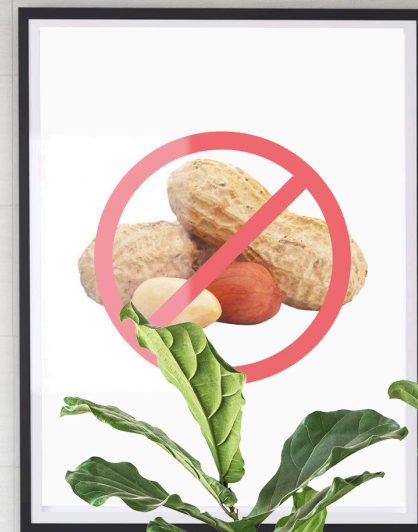
# Arlo finds out how to take PALFORZIA





**The next week Arlo went back to the doctors.  
He was excited to start taking his PALFORZIA.**

**“Welcome back. Before I start giving you your  
PALFORZIA, let me tell you how you should take  
it at home. Always get your parents or a grown-  
up to help you take PALFORZIA.”**



The doctor described to Arlo and his parents how and when he should take PALFORZIA:



- ✓ **You will need to take PALFORZIA every day.**  
At roughly the same time each day.  
With your evening meal is best.

✗ **You must not swallow the capsules.**

✓ **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.**



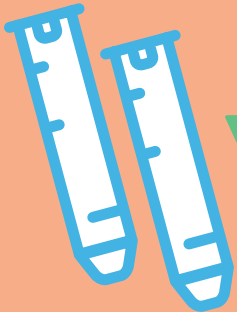
## Section 2

Arlo finds out how to take PALFORZIA

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**X** You should still avoid peanuts, or food that contains peanuts.



**✓** Always carry your adrenaline autoinjectors.

**X** Make sure that you haven't been running around or doing exercise.

Right before or for 3 hours after you take your PALFORZIA.







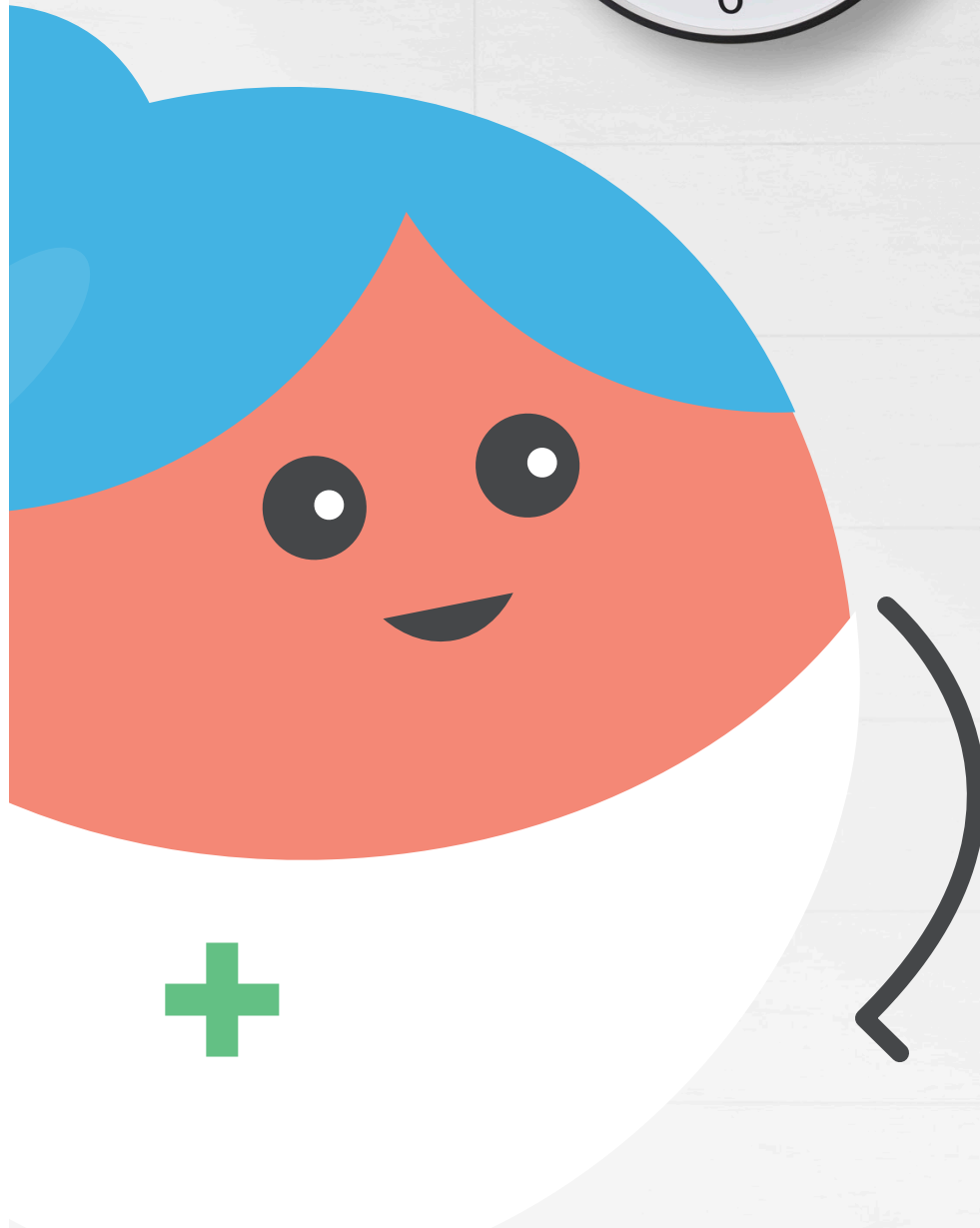
**X** Make sure that you don't have a hot bath or shower right before or for 3 hours after you take your PALFORZIA.

**✓** Wait at least 2 hours after eating PALFORZIA before you go to sleep.



**Thanks, that's really useful.**

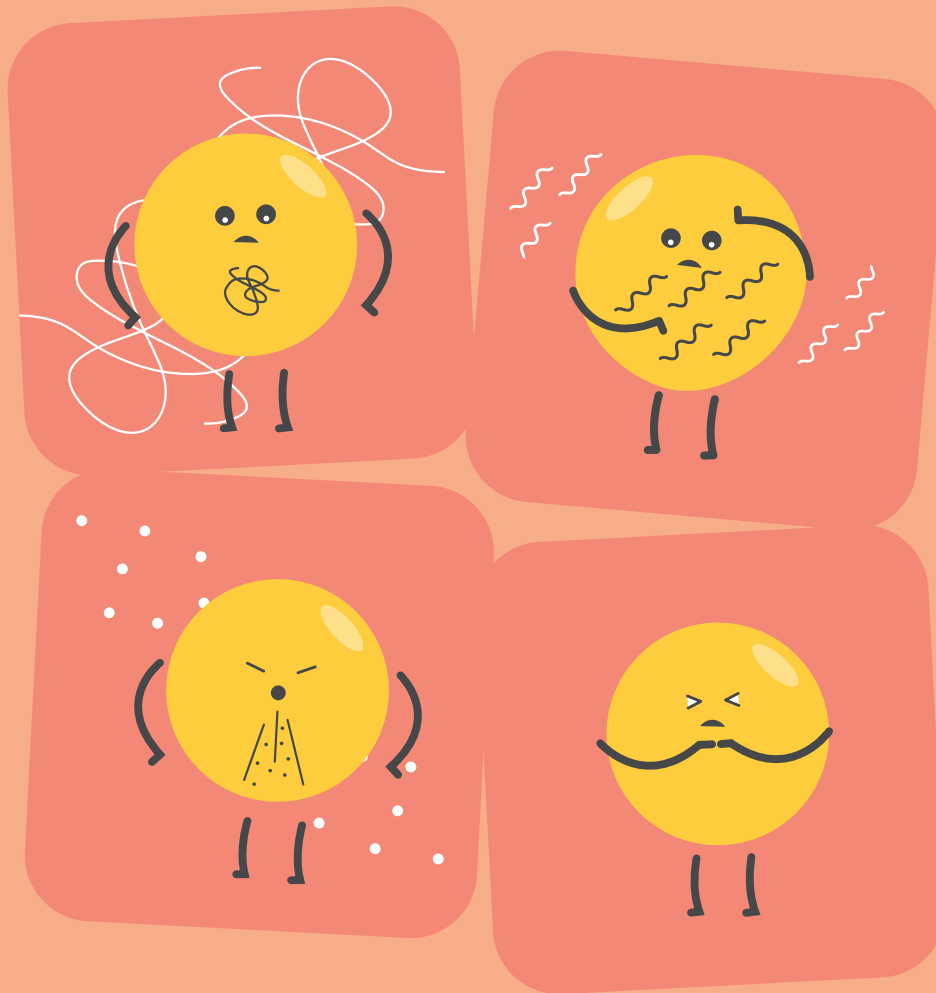




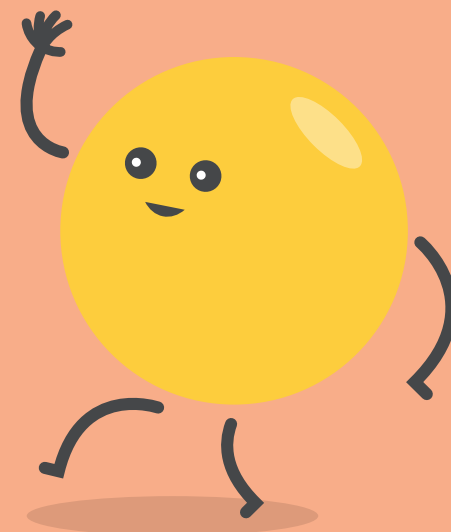
**Some people get side effects of taking PALFORZIA,” continued the doctor. “A side effect is a feeling or symptom that the medicine gives you, which it isn’t supposed to. Some people feel sick when they take it. Some people feel itchy. Some get a tummy ache, some feel sneezy. And others feel wheezy.”**

**“Some people find it hard to swallow or breathe. A few have anaphylaxis and need an injection of adrenaline to make them feel better. Others have something called EoE. Their doctor helps them in all cases.”**

**“If you do feel any of those things, or any other things that make you feel unwell, it’s very important that you tell your parents or another grown-up quickly.”**



**Okay doctor. I will.**



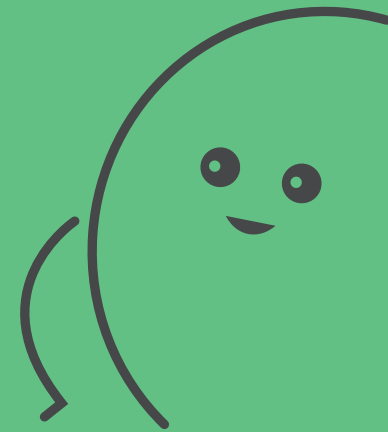
**Section 2**

Arlo finds out how to take PALFORZIA

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3

# Arlo takes PALFORZIA for the first time





**Now Arlo was ready to start taking his PALFORZIA.**

**“Because you’ve never had PALFORZIA before, today you need to take it 5 times in a row during this visit” said the doctor.**

**“I’ll put it in your food, just like you will do at home. We will have a break of 30 minutes between each dose, just to check that you are okay. And the amount of PALFORZIA will start off really small and gradually get bigger. Remember to let me or your parents know if you don’t feel well.”**



### Section 3

Arlo takes PALFORZIA for the first time

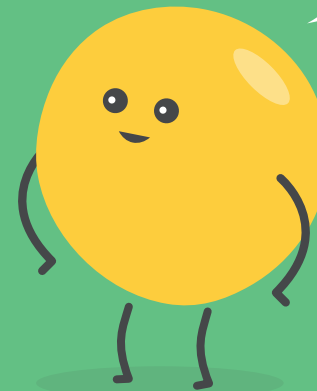
Booklet\_7-11\_IE Version 1.0\_June 2022. PALF-NP-IE-0003.

So Arlo took his PALFORZIA 5 times. And each time he rested for 30 minutes in between. Once he had finished all of the PALFORZIA for that day, and he had waited to see if he still felt well, he was ready to go home.

**Come back tomorrow so I can check how you feel, and give you some more PALFORZIA.**



**See you tomorrow doc.**



4

# Arlo's second day taking PALFORZIA



The next day Arlo went back to see the doctor.

“Hello again Arlo,” said the doctor.  
“How are you feeling today?”

“I feel great!” replied Arlo with a smile.

“That’s good news!” said the doctor.  
“Today I will give you your PALFORZIA once more before you go home.”

“But before you go, here is a special card with your name on it. Always carry this around with you in your pocket. It tells people that you are taking PALFORZIA and that you have adrenaline autoinjectors. You should show it to a grown-up if you have to go to the doctors or hospital.”

“I can put it in my school bag, or keep it in my coat pocket, with my adrenaline,” replied Arlo.

**Patient Card**

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Address: \_\_\_\_\_ Date of birth: \_\_\_\_\_

Emergency contact #1: \_\_\_\_\_ Phone: \_\_\_\_\_

Emergency contact #2: \_\_\_\_\_ Phone: \_\_\_\_\_

This person is **PEANUT-ALLERGIC** and is receiving **PALFORZIA®** (defatted powder of *Arachis hypogaea* L., semen [peanuts]), to treat peanut allergy. Adverse reactions (including **ANAPHYLAXIS**) with this immunotherapy can be severe and may require emergency treatment with **ADRENALINE** which this person should carry with them at all times.

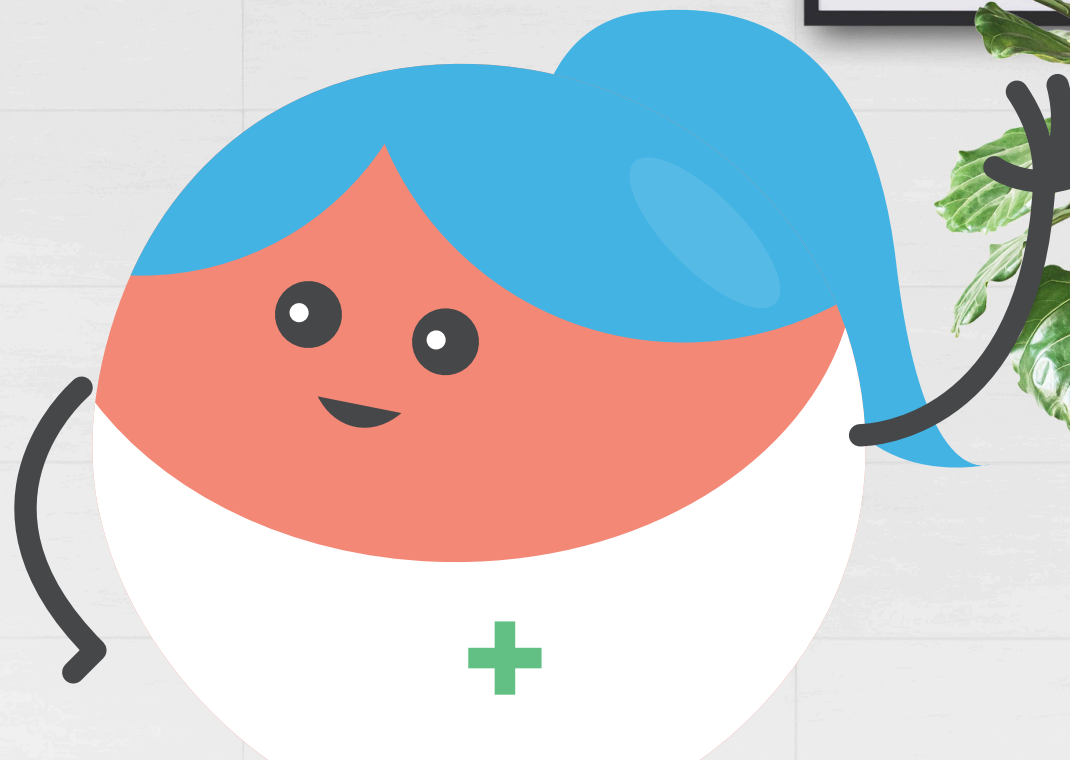
If you suspect that this person is having **ANAPHYLAXIS**, give a dose of **ADRENALINE** according to the instructions on the adrenaline autoinjector, and contact **EMERGENCY SERVICES** on 999 **immediately**. Common symptoms of **ANAPHYLAXIS** include: abdominal pain, itching, hives, rash, nausea, vomiting, throat tightness/closure, shortness of breath, wheezing, coughing, dizziness, passing out, and weak pulse.

PALFORZIA® Patient Card\_IE version 1.0\_June 2022. PALF-NP-IE-0001.



**“Exactly!” replied the doctor. “Okay Arlo - I’ve given your PALFORZIA. You can go home now. I’ll see you in 2 weeks to check how you’re doing. Don’t take any PALFORZIA on that day before you come and see me. And if you do feel unwell, tell your parents,”** reminded the doctor.

**Goodbye for now.**



#### **Section 4**

Arlo’s second day taking PALFORZIA

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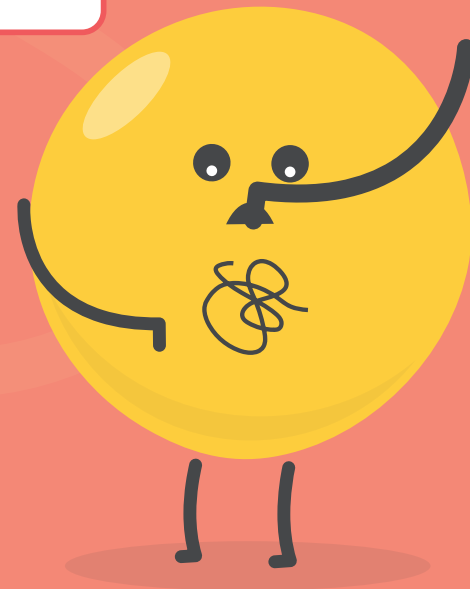
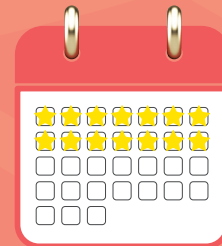
# 5 Arlo gets a tummy ache


Arlo took his PALFORZIA every day and every 2 weeks he went back to the doctors for a slightly bigger dose.

One time when Arlo took his daily dose, he had a tummy ache. He felt worried that the PALFORZIA was making him feel like this, so he told his parents.

Arlo's parents explained this to the doctor.

"I'm sorry to hear that, Arlo," said the doctor.

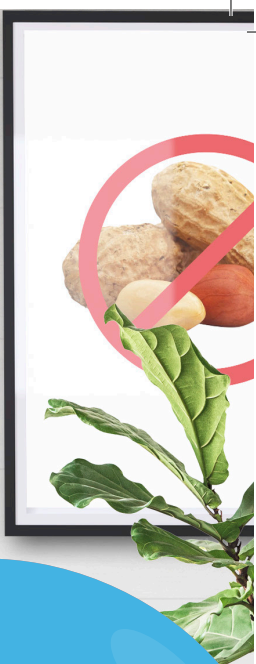




The doctor gave Arlo a little bit less PALFORZIA this time, and waited for an hour or so to see how Arlo felt. With Arlo seeming okay, the doctor said he was fine to go home and take a lower dose for 2 weeks.

For the next 6 months, Arlo kept coming back to the doctors every 2 weeks.

He gradually increased how much PALFORZIA he was taking. A couple of times his tummy ache came back, so he had to stay on the same dose for a few more weeks of PALFORZIA, which is called the Maintenance dose. But eventually he ended up on the full dose. And most importantly, he still never ate any peanuts and always carried his adrenaline autoinjectors.



## Section 5

Arlo gets a tummy ache



## 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](mailto:info.ie@aimmune.com)

## Medical information and safety reporting

Email: [medinfo-eu@aimmune.com](mailto:medinfo-eu@aimmune.com)

Tel: +353 (0) 15827964

