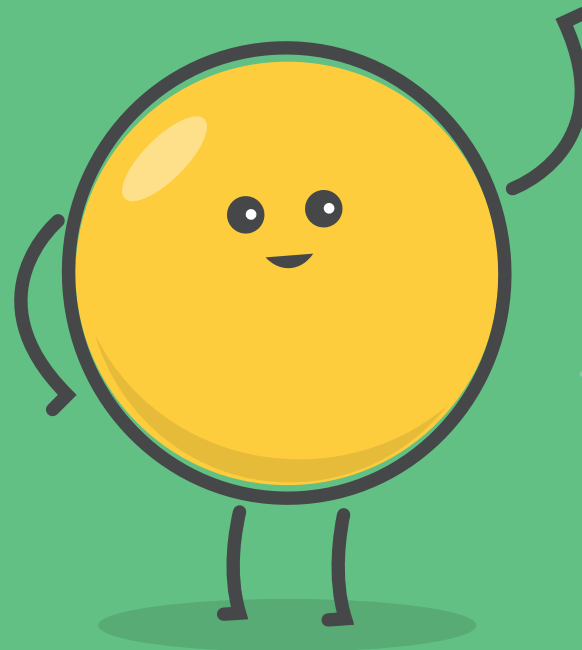


# PALFORZIA<sup>®</sup> and you

Important safety information  
for PALFORZIA<sup>®</sup> ▼  
(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 4-6 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.

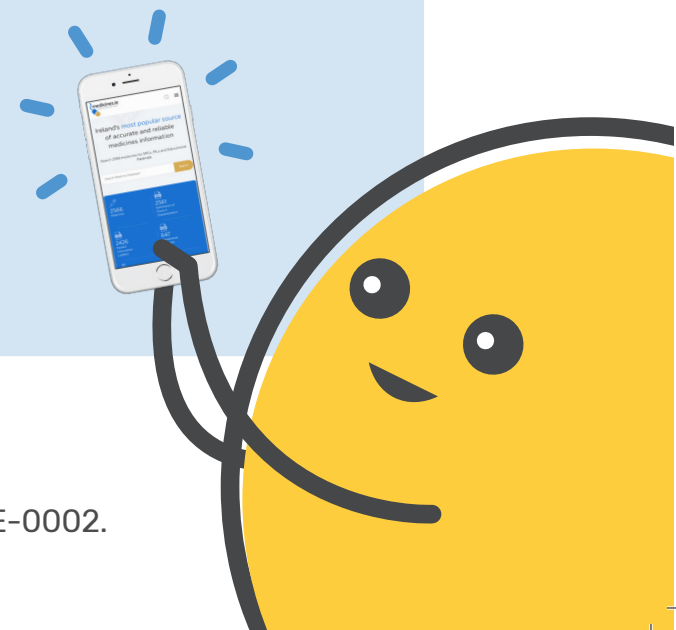
# For Caregivers: About this booklet

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 7** **Section 1:** Arlo and PALFORZIA

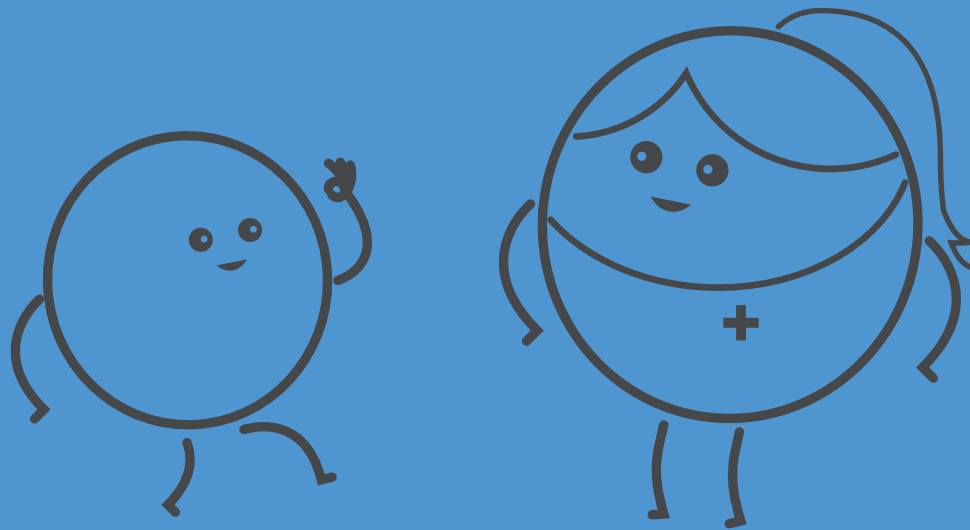
**Page 15** **Section 2:** Arlo takes PALFORZIA for the first time

**Page 20** **Section 3:** Arlo's second day taking PALFORZIA

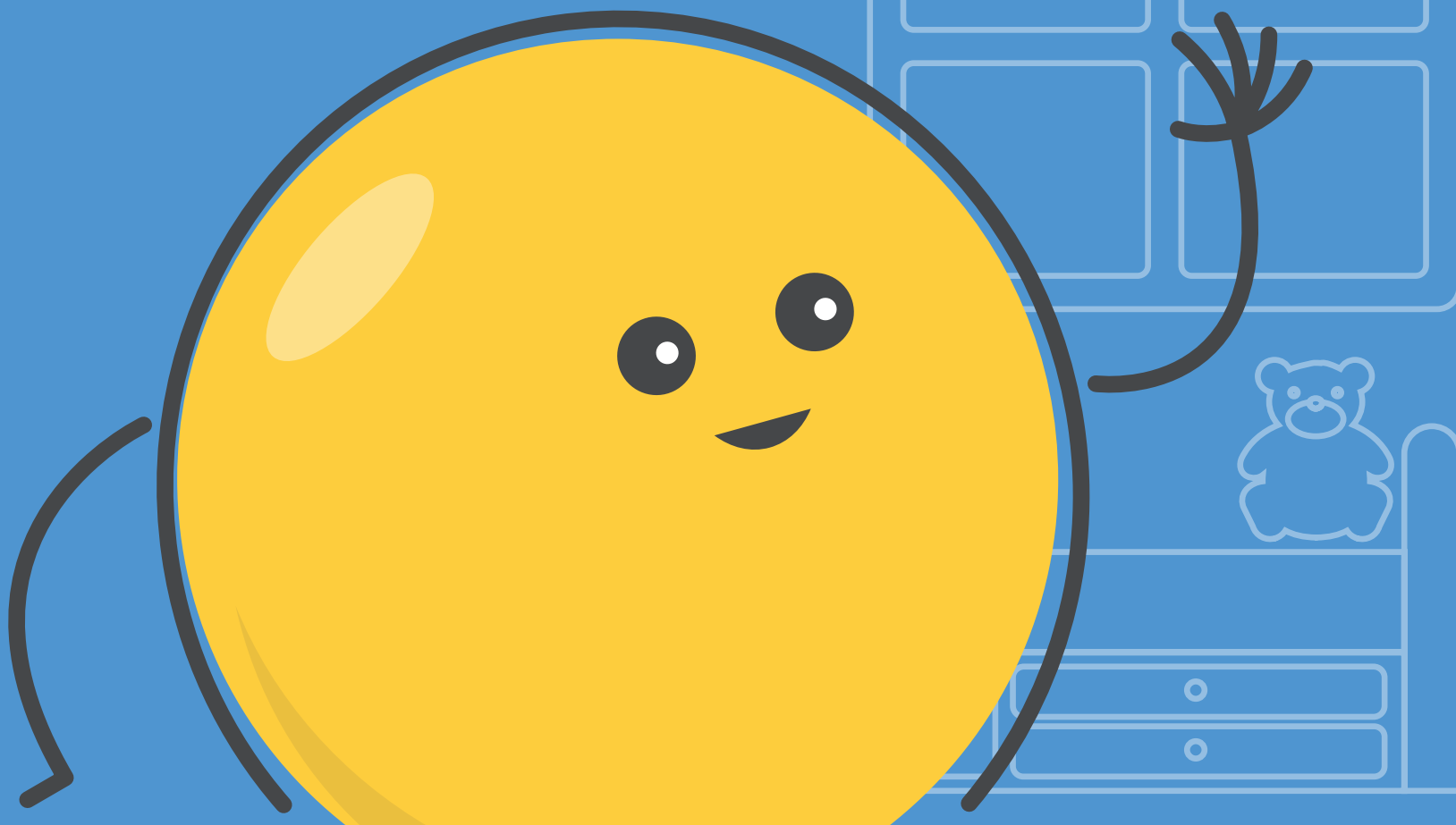
**Page 25** **Section 4:** Arlo gets a tummy ache

1

# Arlo and PALFORZIA

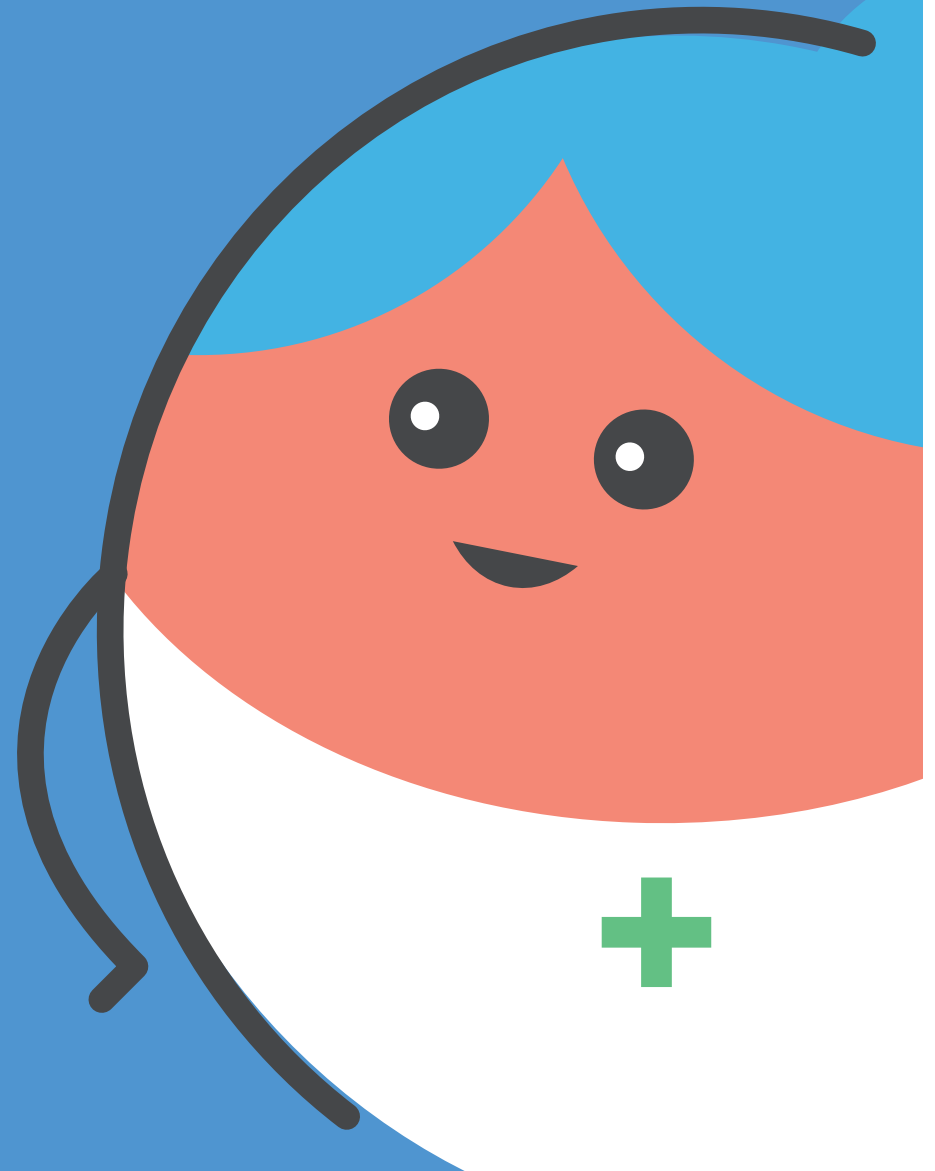


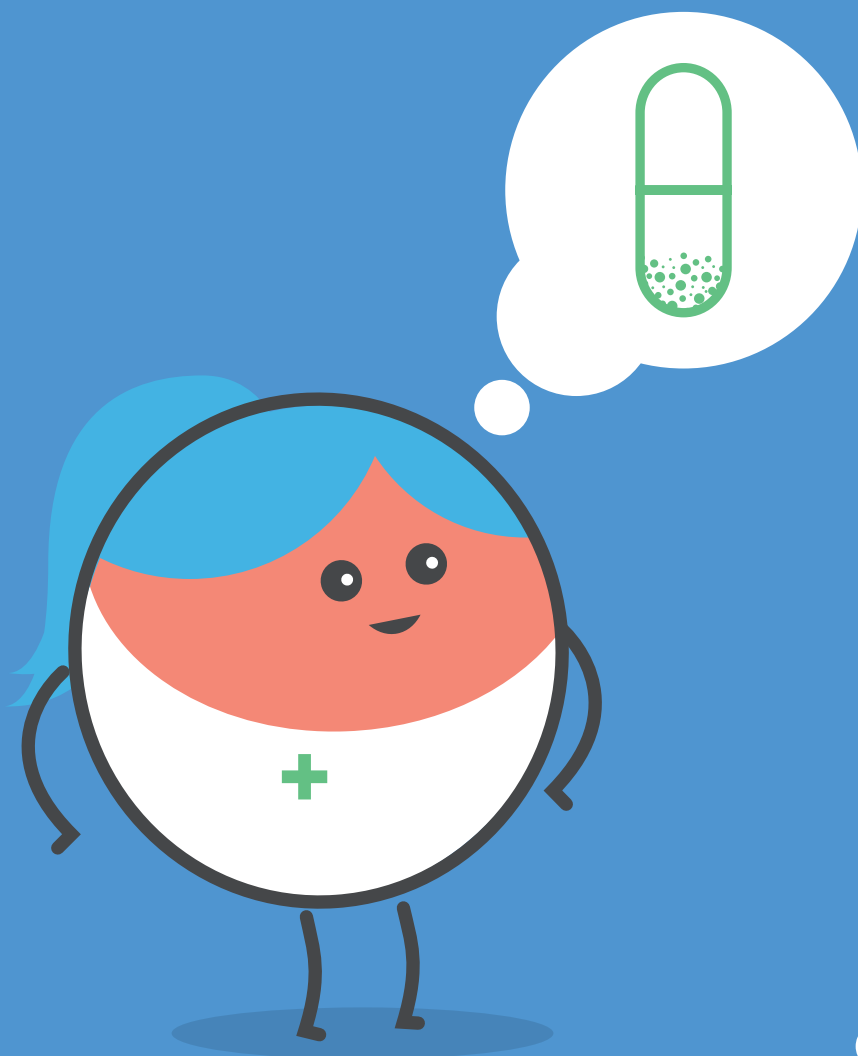
**This is Arlo! He has a peanut allergy  
and his doctor has prescribed him  
a medicine called PALFORZIA.**





One day, Arlo's parents took him to the doctors to learn about important safety information for PALFORZIA.





**"Hello Arlo," said the doctor.**

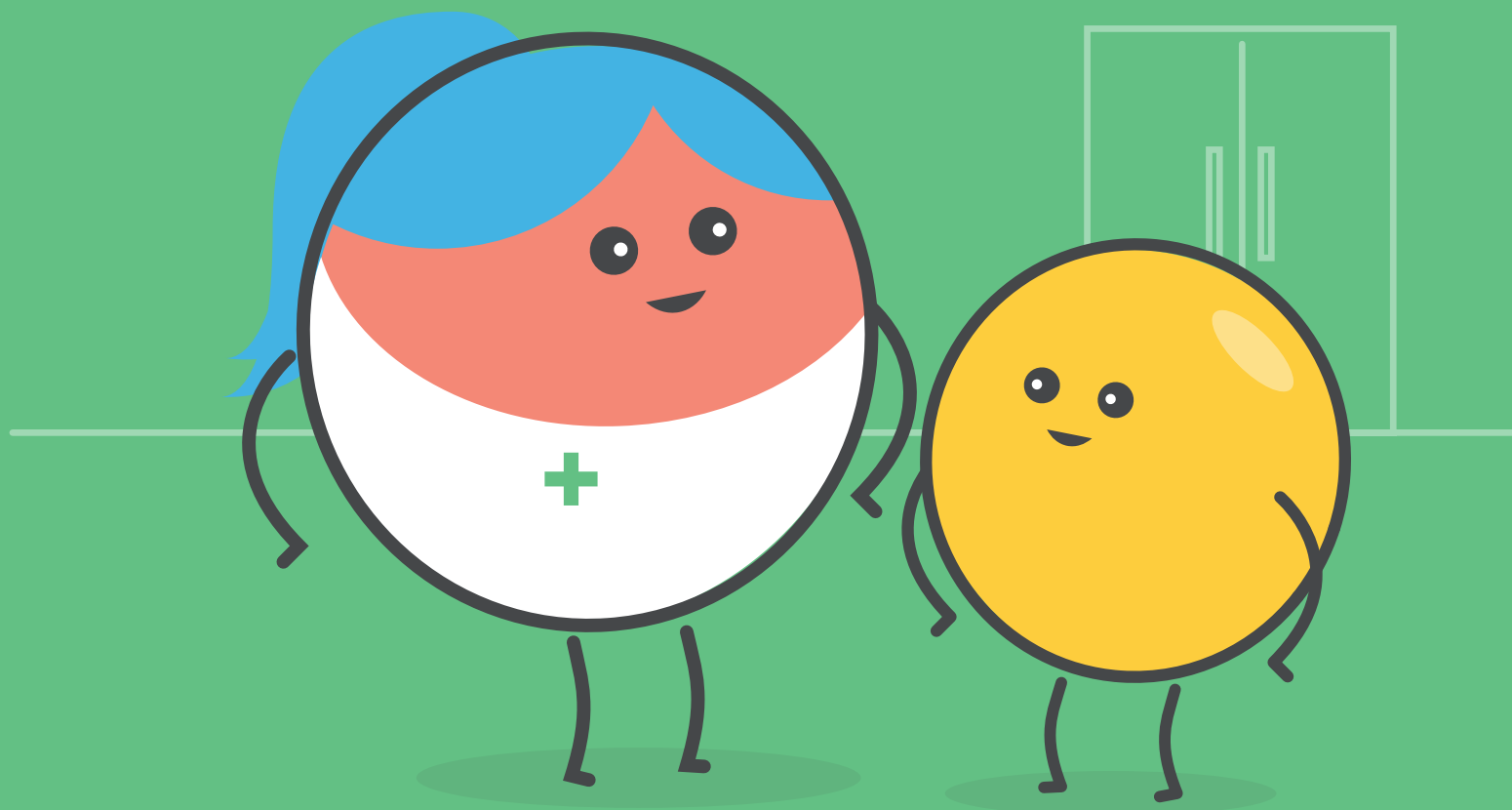
**"There are some very important things to remember now that you are taking PALFORZIA."**

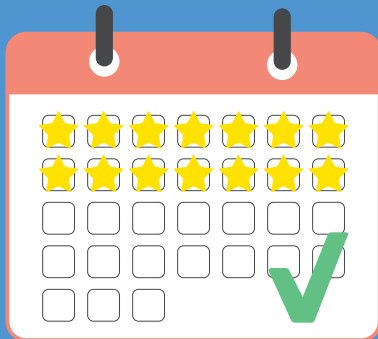
**"You must remember to never eat peanuts and to always keep your adrenaline with you. Your adrenaline autoinjectors will help you if you feel very unwell because of peanuts."**

**"Thank you doctor!" said Arlo.**



"That's great!" said the doctor.  
"Now let's talk about how you  
should take your PALFORZIA."





**“You need to take your PALFORZIA once a day, every day” said the doctor.**

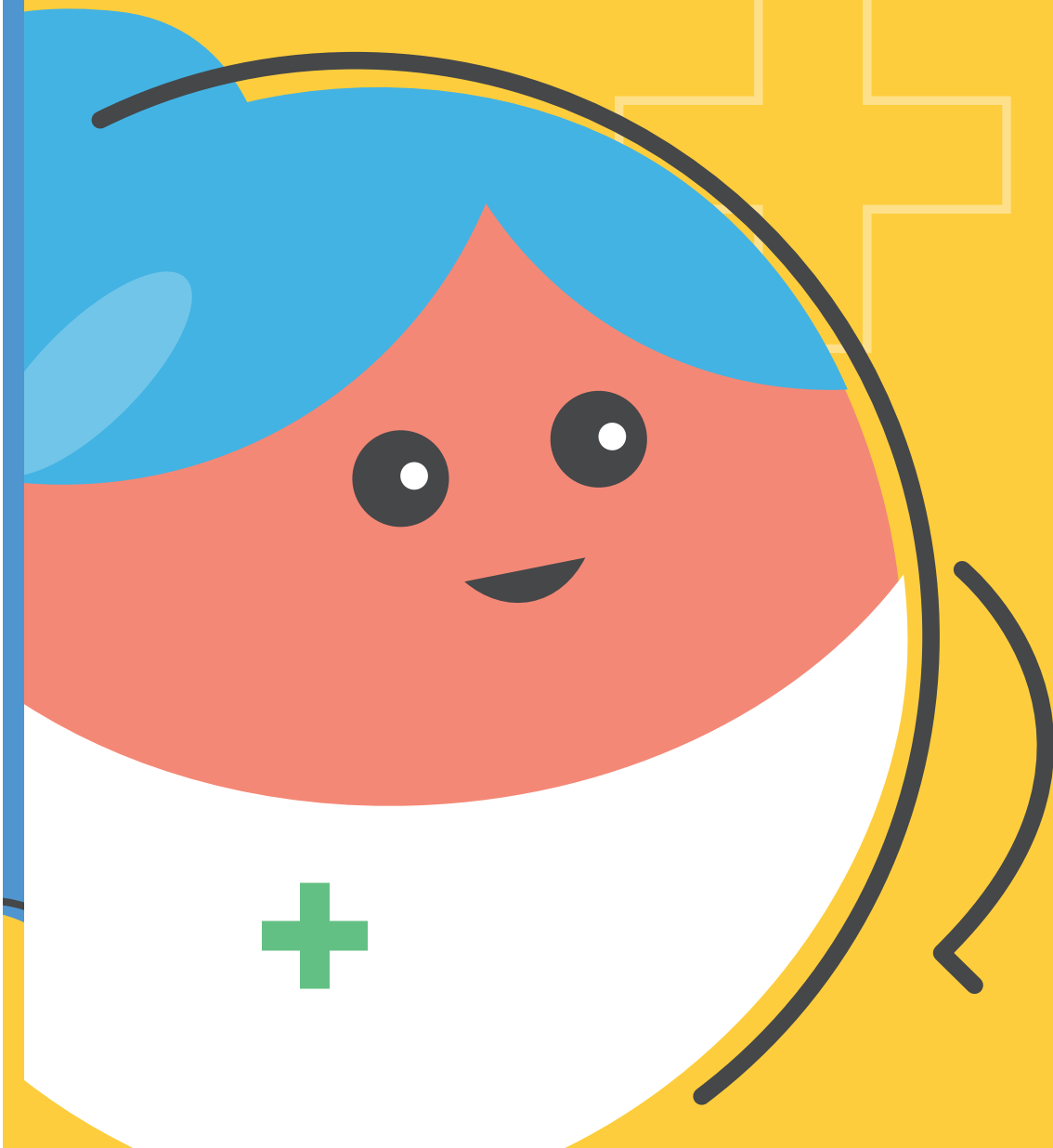
**“Yes doctor, I will remember to take my PALFORZIA every day,” replied Arlo.**



**“And you need to take it with some food that you aren't allergic to. With your evening meal is best,” said the doctor.**

**“Yes doctor, I will make sure my PALFORZIA is mixed in some food,” replied Arlo.**





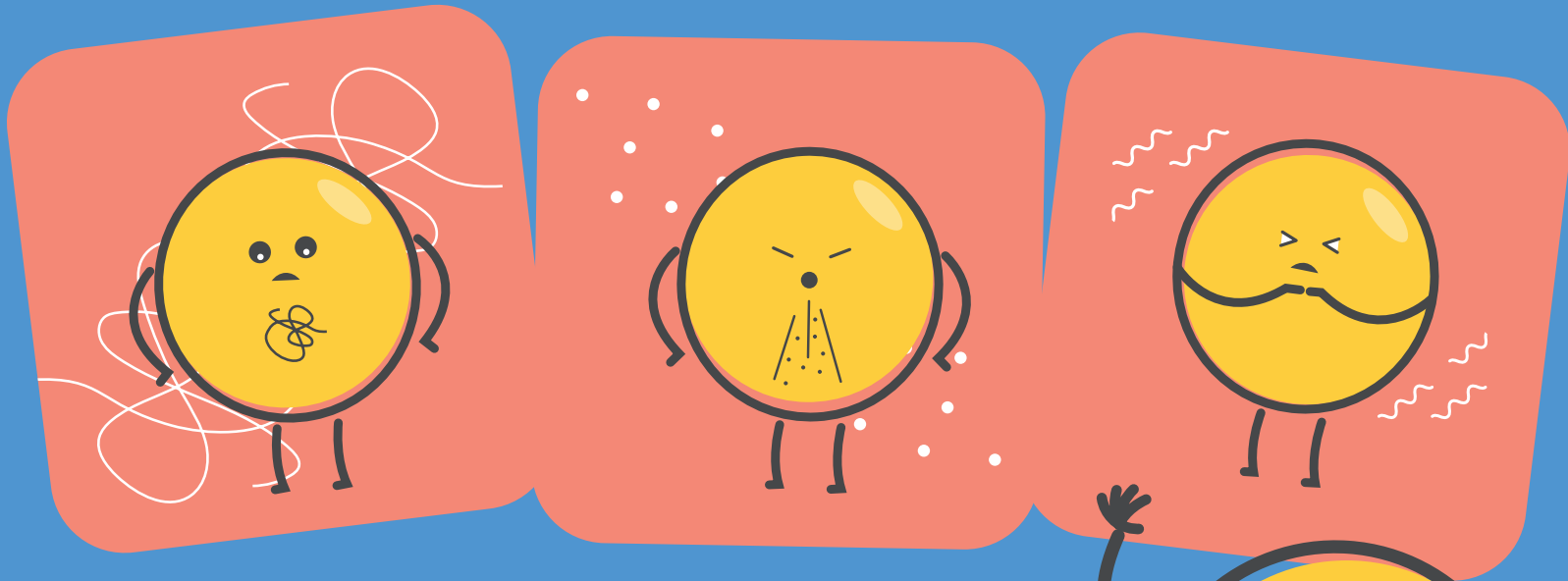
**“Now, Arlo, I need to tell you something else about your PALFORZIA,” said the doctor.**

**“Some people feel sick after they take the medicine. Some people feel itchy. Some feel sneezy. And others feel wheezy.”**

**“Some people find it hard to swallow. Or get a pain in their chest or a tummy ache. And some need an injection of their adrenaline autoinjector to make them feel better. Remember to always carry 2 adrenaline autoinjectors.”**

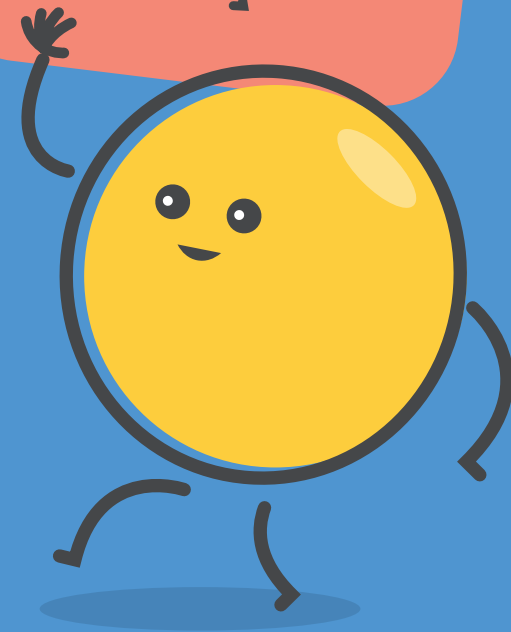
**Section 1**

Arlo and PALFORZIA



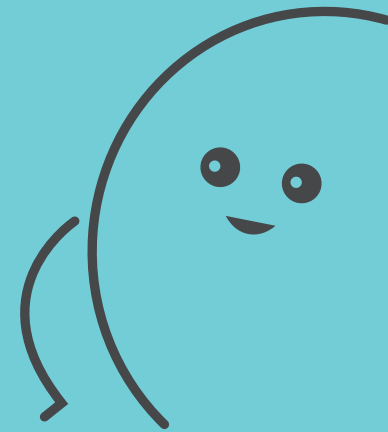
**“If you do feel any of those things, or any other things that make you feel unwell, it’s very important that you tell your mummy, daddy or another grown-up quickly.”**

**“Okay doctor,” said Arlo. “I will.”**

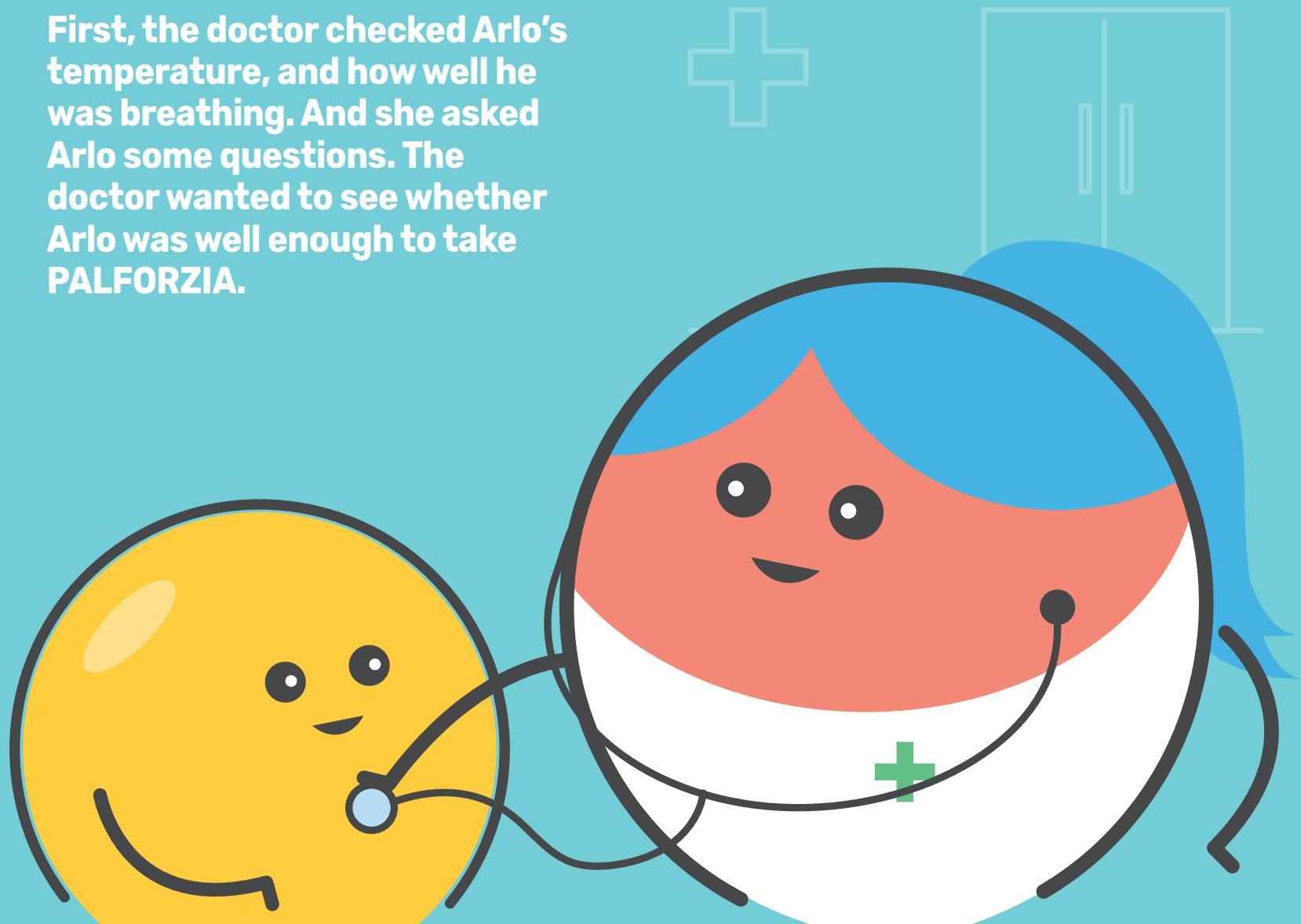


2

# Arlo takes PALFORZIA for the first time



**First, the doctor checked Arlo's temperature, and how well he was breathing. And she asked Arlo some questions. The doctor wanted to see whether Arlo was well enough to take PALFORZIA.**





**“Because you’ve never had PALFORZIA before, today you need to eat it 5 times in a row during this visit,” said the doctor. “It’s a powder. I’ll put it in your food so you can eat it. Remember to let me or your parents know if you don’t feel well.”**



## Section 2

Arlo takes PALFORZIA for the first time

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So Arlo ate his PALFORZIA and food, and then had a little rest. Then he ate some more, and had another rest. And then again, and again, and again.

And when all of the PALFORZIA had gone and he'd sat at the doctor's for an hour, Arlo was ready to go home.



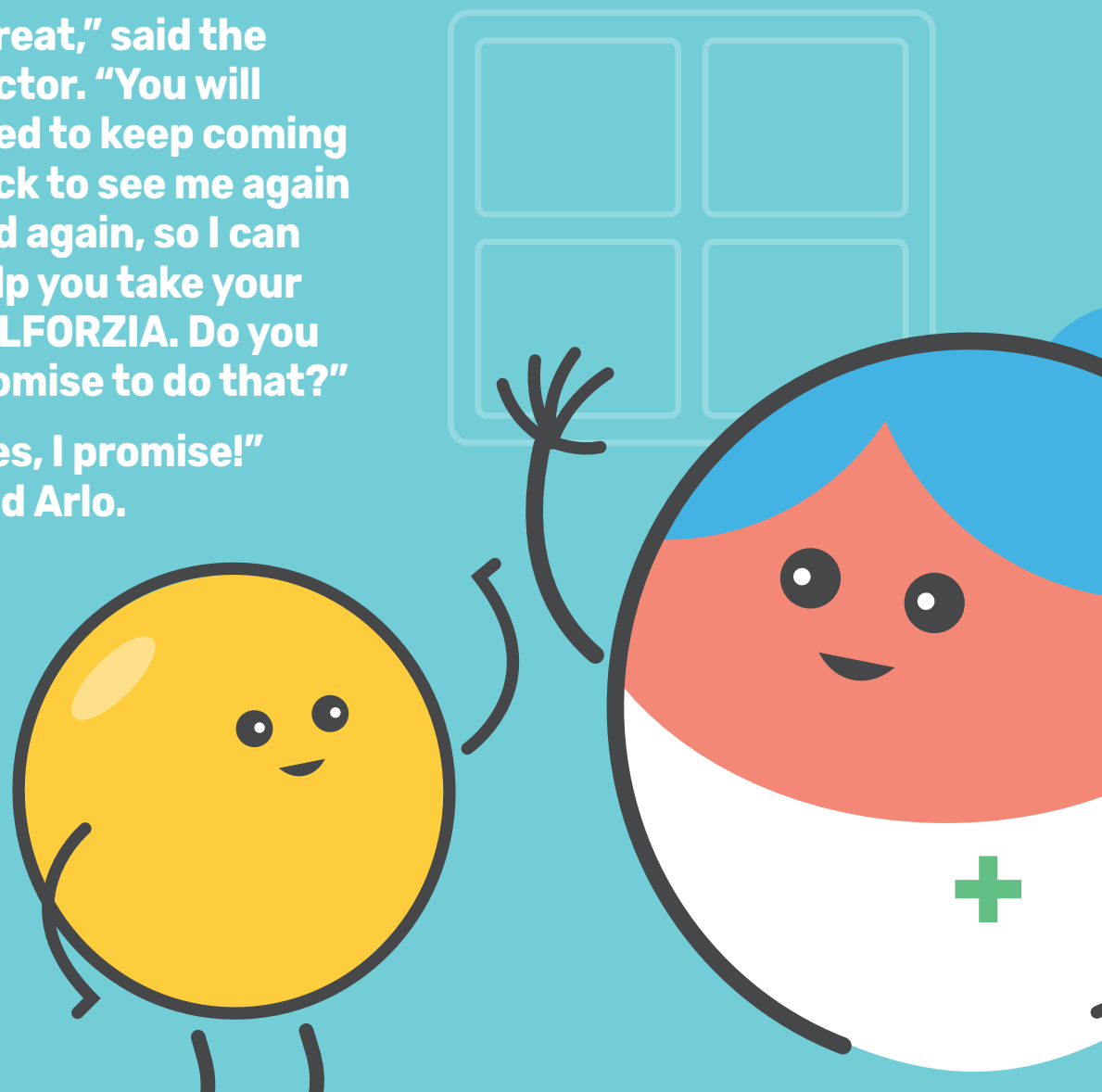
**“You’ve taken all of your PALFORZIA for today. Well done,” said the doctor.**

**“But remember to come back tomorrow so I can check how you feel.”**

**“Yes doctor, I will,” replied Arlo.**

**“Great,” said the doctor. “You will need to keep coming back to see me again and again, so I can help you take your PALFORZIA. Do you promise to do that?”**

**“Yes, I promise!” said Arlo.**



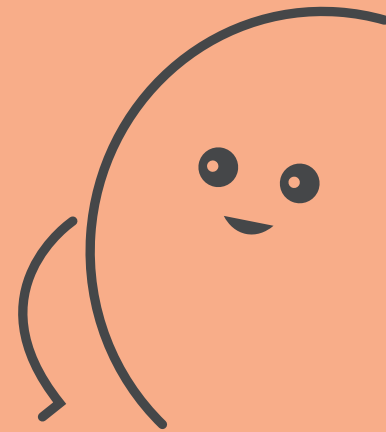
**Section 2**

Arlo takes PALFORZIA for the first time

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3

# Arlo's second day taking PALFORZIA

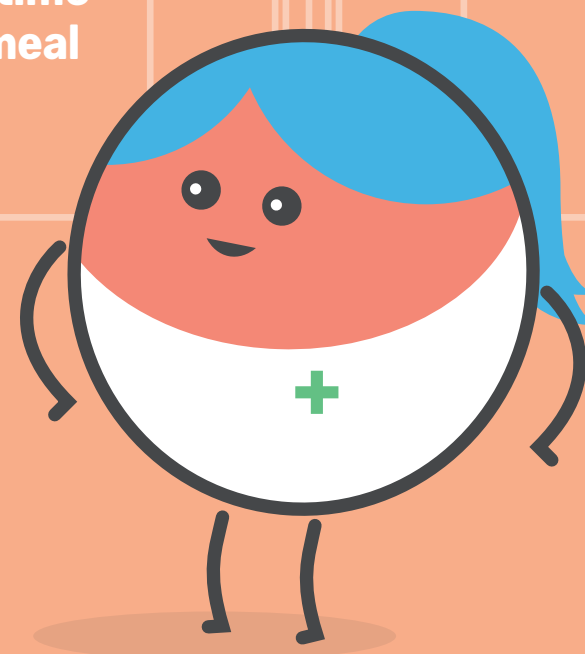
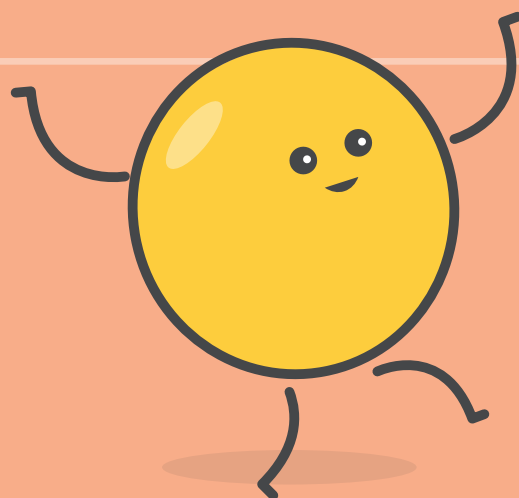
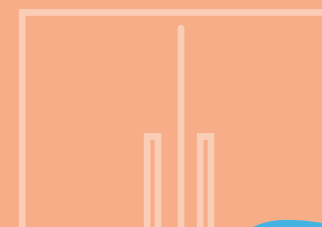


The next day Arlo went back to see the doctor.

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

“I feel great!” replied Arlo.

“That’s good news!” said the doctor. “Today I will give you your PALFORZIA once more before you can go home. Then, from tomorrow, you’ll need to take the PALFORZIA once a day at roughly the same time at home with food. Taking it with your evening meal might be best... I know how you like to eat!”



### Section 3

Arlo’s second day taking PALFORZIA

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**“Remember, if you’ve been running around or playing, you need to wait a little while until you’ve calmed down before you take your PALFORZIA.”**



**"And remember that you shouldn't run around or have a hot bath or shower right before or for 3 hours after you take your PALFORZIA," said the doctor.**

### **Section 3**

Arlo's second day taking PALFORZIA

Booklet\_4-6\_IE Version 1.0\_June 2022. PALF-NP-IE-0002.

**“One last thing Arlo. Here is a special card with your name on it. Always carry this around with you in your pocket. It tells people that you have a peanut allergy, 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.”**

**“Yes I will – then people will know that peanuts make me sick,” replied Arlo.**

**Patient Card**

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

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

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

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

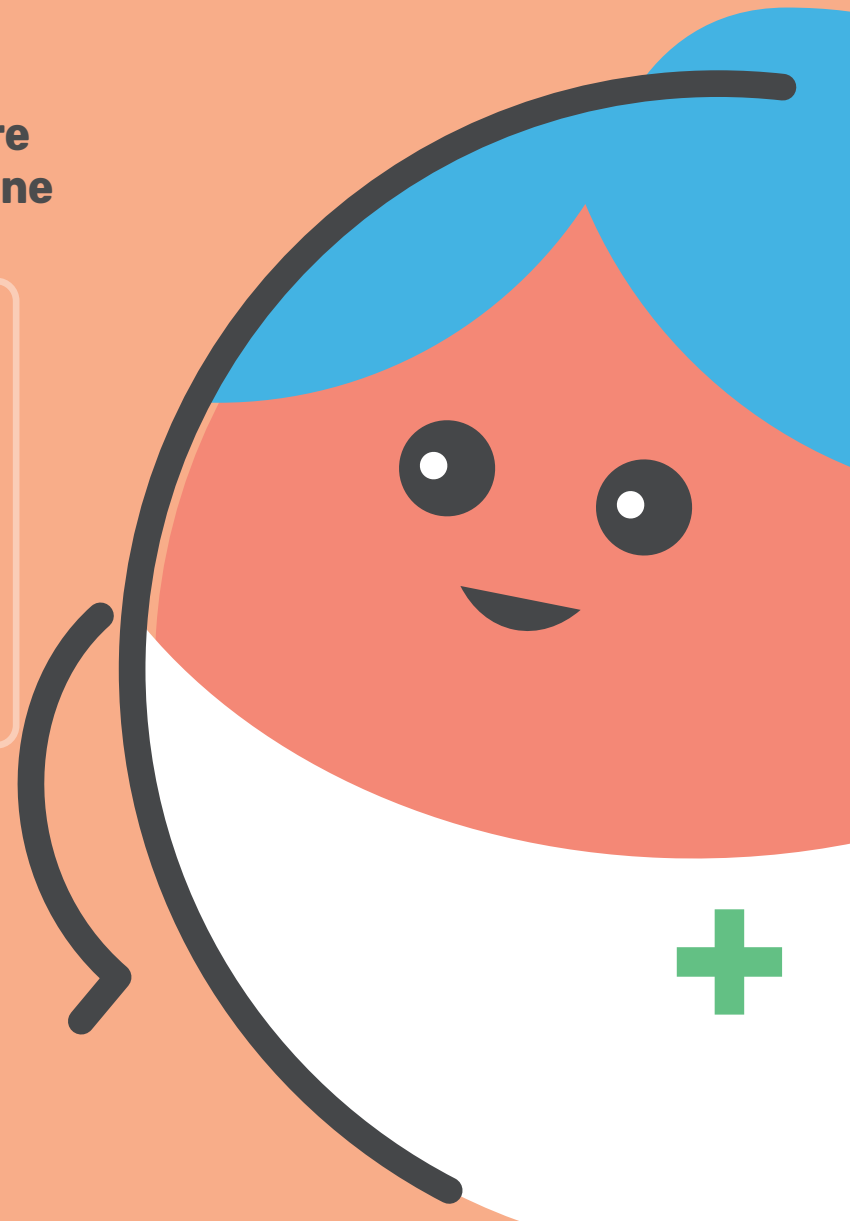
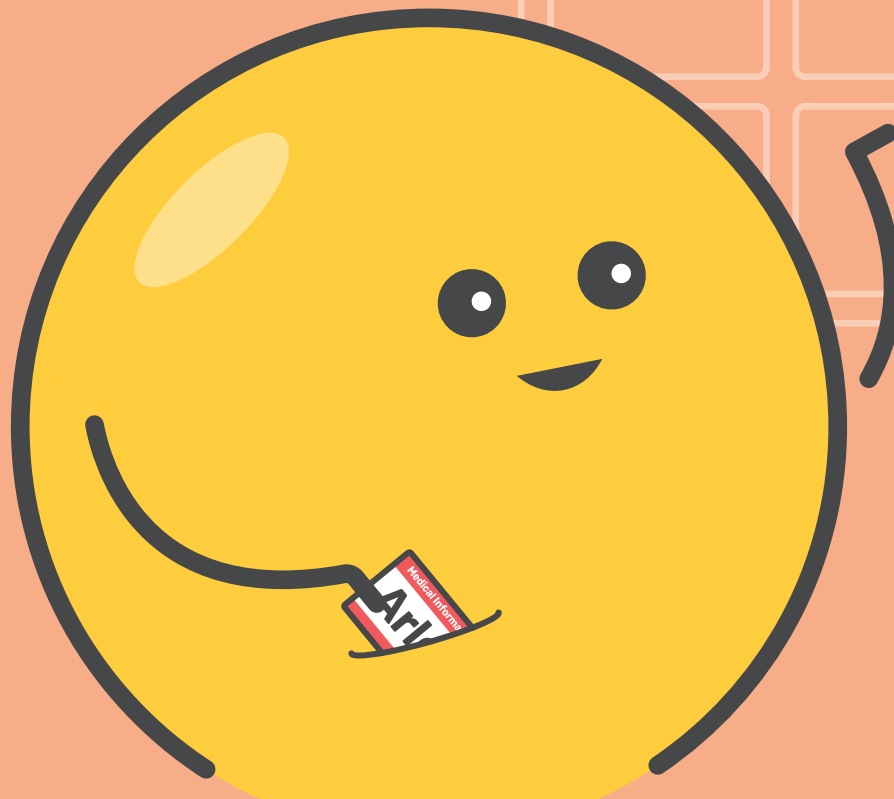
This person is **PEANUT-ALLERGIC** and is receiving **PALFORZIA®** (defatted powder of *Arachis hypogaea* L., semen [peanuts]), to treat peanut allergy. Adverse reactions (including **ANAPHYLAXIS**) with this immunotherapy can be severe and may require emergency treatment with **ADRENALINE** which this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



**“That’s right! Okay Arlo – you can go home now. I’ll see you in 2 weeks to check how you’re doing. And don’t forget to carry your adrenaline autoinjectors” said the doctor.**



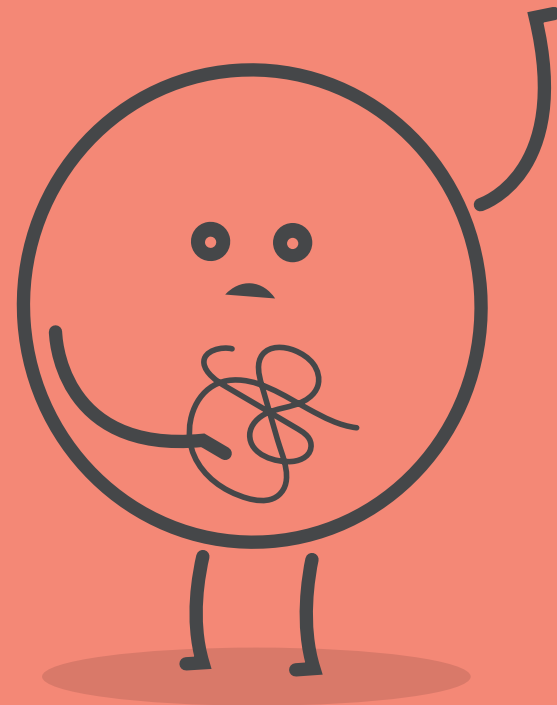
### **Section 3**

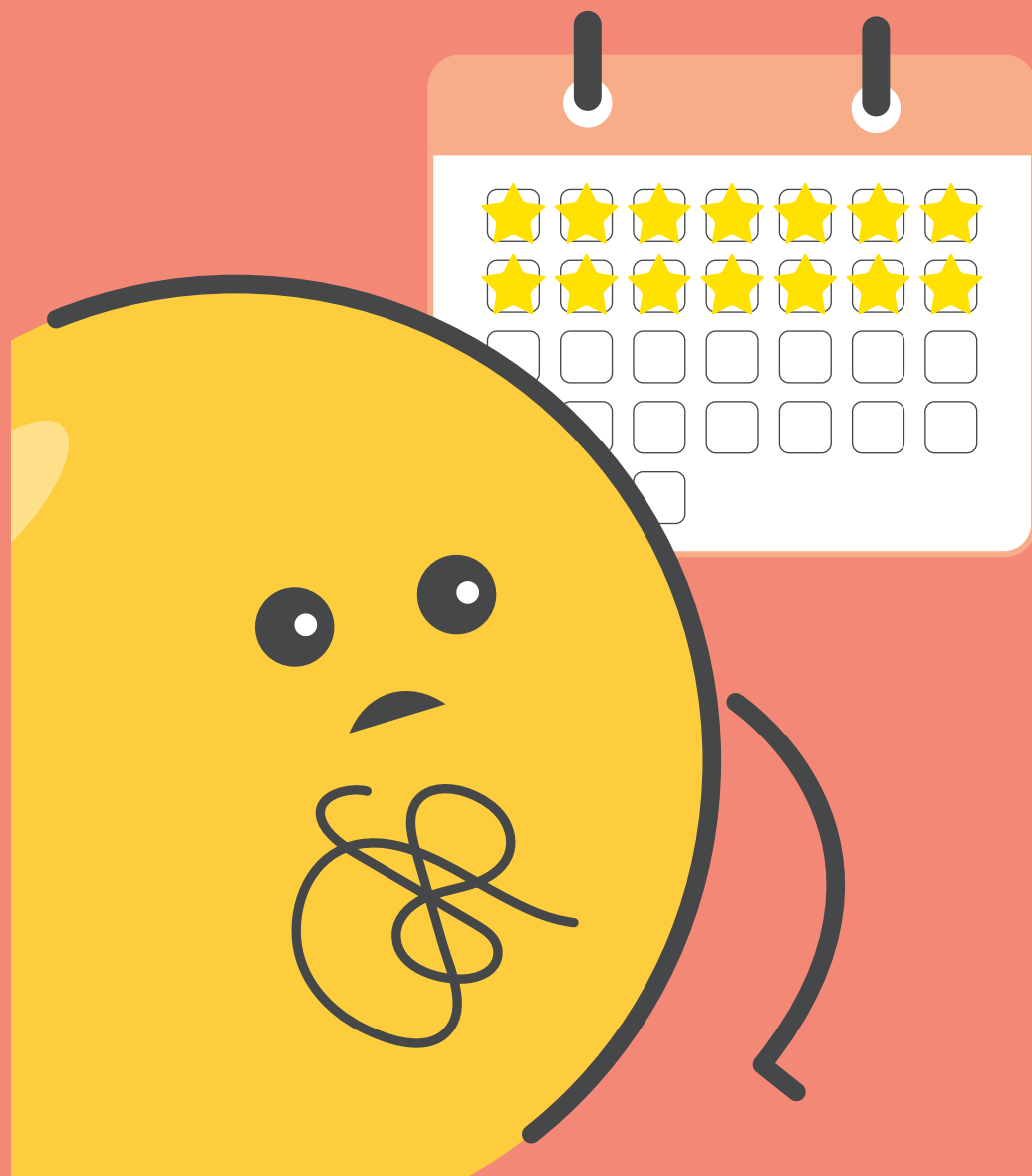
Arlo’s second day taking PALFORZIA

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4

# Arlo gets a tummy ache





Every 2 weeks, Arlo went back to the see the doctor. The doctor asked how Arlo was feeling and if everything was okay, he was given a little bit more PALFORZIA.

One time when he was taking his PALFORZIA, Arlo had a tummy ache. He told his parents and they went to the doctor to see if everything was okay.

The doctor asked: "Have you been taking you PALFORZIA once a day?"

"Yes, every day!" replied Arlo.

"And how did your PALFORZIA make you feel?" asked the doctor.

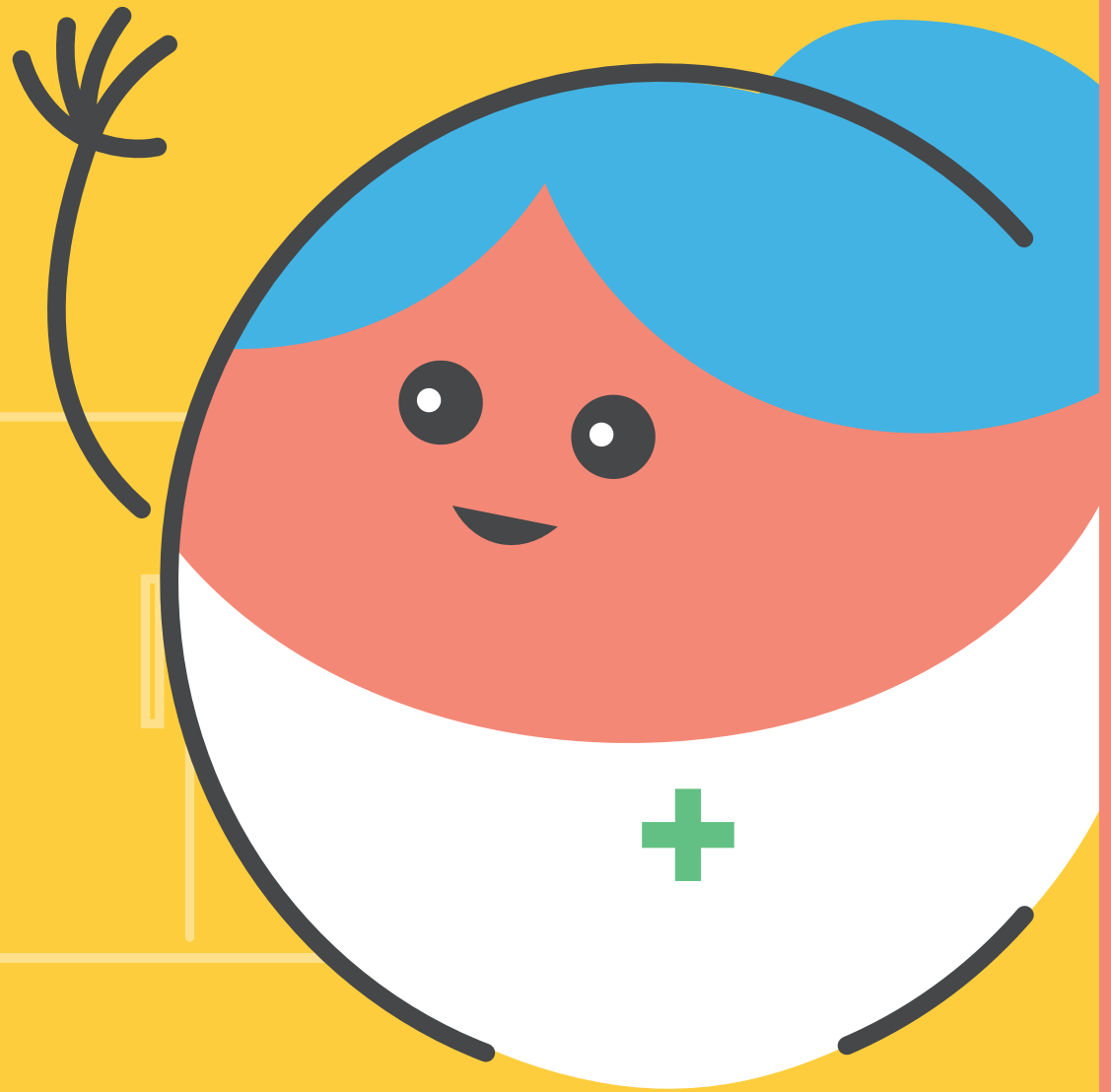
#### Section 4

Arlo gets a tummy ache

**“Well,” said Arlo, with a frown. “At first I felt great. But today I have had a tummy ache. It hurt and made me cry. So I told my parents, like you asked me to.”**

**“I’m sorry to hear that, Arlo,” replied the doctor. “But I’m glad you told your parents – and me too. I will give you less PALFORZIA until I can be sure that you feel better.”**

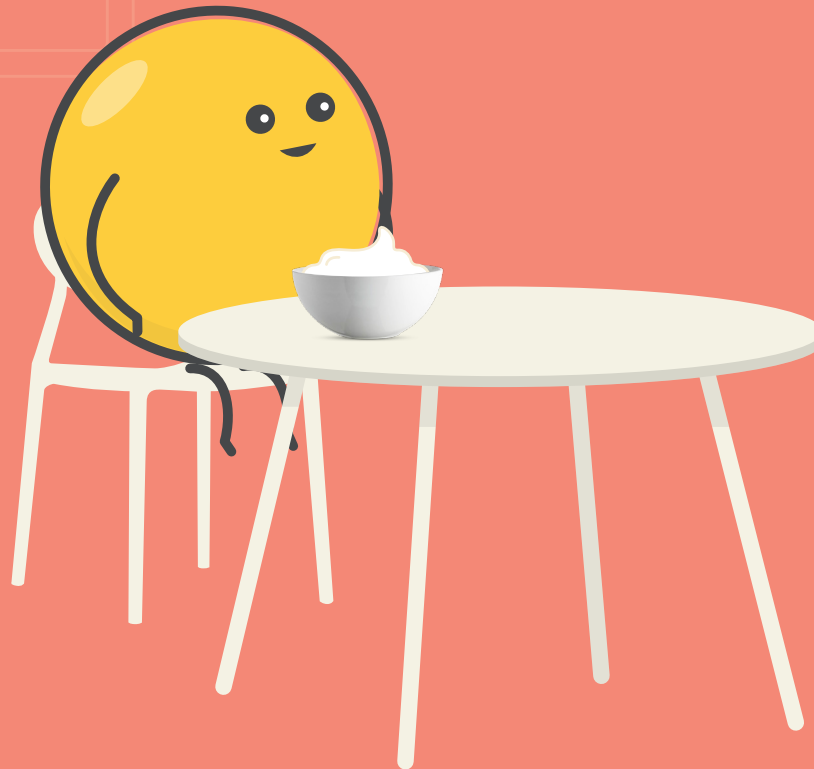
**The doctor gave Arlo just a little bit of PALFORZIA and asked him to come back again in 2 weeks.**





**Arlo's tummy ache went away and every 2 weeks he went back to see the doctor.**

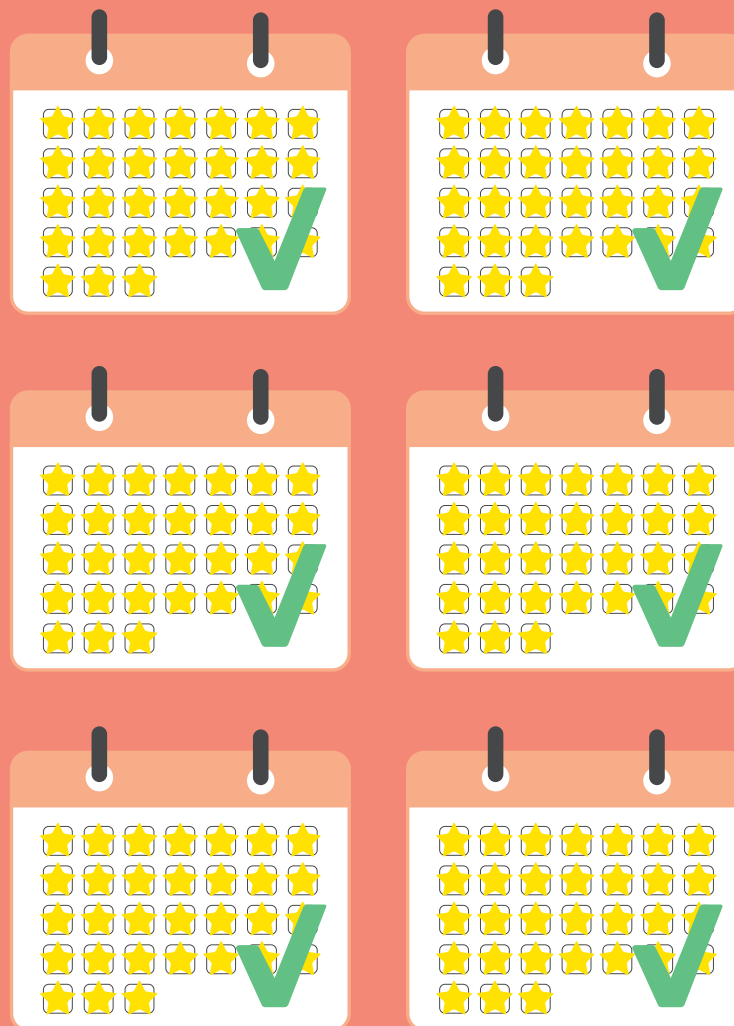
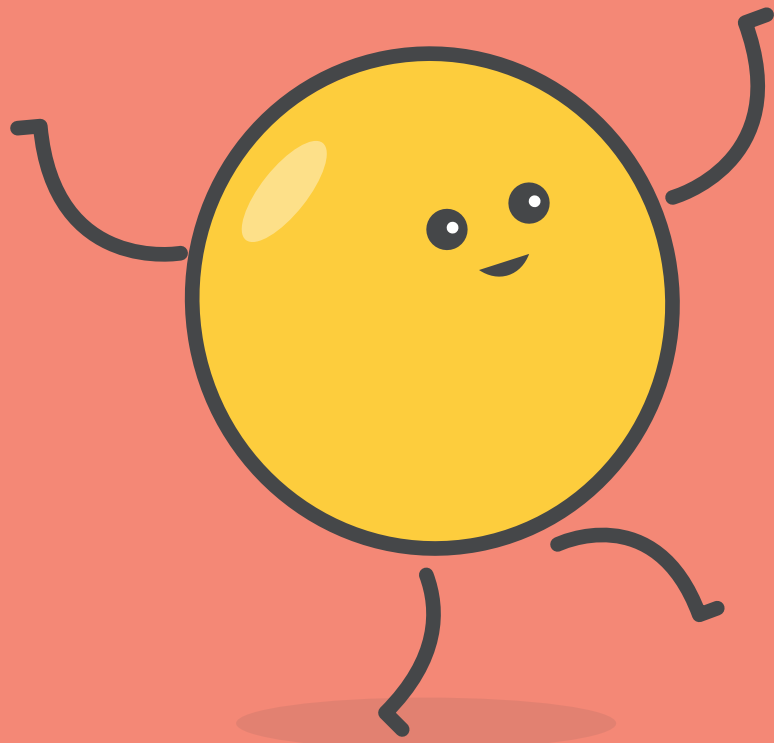
**Each time the doctor checked that the tummy ache hadn't come back.**



**Section 4**

Arlo gets a tummy ache

After about 6 months, Arlo had reached the Maintenance dose of PALFORZIA.



**Now he doesn't see the doctor as much but he still remembers that he has to do these important things:**



- **Mix his PALFORZIA into a little bit of food and take it once a day, every day**



- **Never eat peanuts or food with peanuts in it**



- **Always carry his adrenaline autoinjectors in case he needs to use them**

**Section 4**

Arlo gets a tummy ache



### **Contact information**

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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

