

## **B. PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### **PALFORZIA 10 mg oral powder in capsules for opening** defatted powder of *Arachis hypogaea* L., semen (peanuts)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What PALFORZIA is and what it is used for
2. What you need to know before you take PALFORZIA
3. How to take PALFORZIA
4. Possible side effects
5. How to store PALFORZIA
6. Contents of the pack and other information

#### **1. What PALFORZIA is and what it is used for**

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

PALFORZIA is intended for children and young people aged from 4 to 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 (desensitisation). PALFORZIA can help reduce the severity of allergic reactions after coming into contact with peanut.

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

You must continue to strictly avoid eating peanuts while taking PALFORZIA.

#### **2. What you need to know before you take PALFORZIA**

##### **Do not take PALFORZIA**

- if you are allergic to any of the excipients (other ingredients) in this medicine (listed in section 6).
- if you have severe asthma or if your asthma is not under control (as assessed by a doctor).
- if you have ever had a problem swallowing or long term problems with your digestive system.
- if you have ever had a severe mast cell disorder (as assessed by a doctor).
- if you had severe or life-threatening anaphylaxis within 60 days before starting treatment.

## Warnings and precautions

Talk to your doctor before taking PALFORZIA and tell your doctor about any medical conditions that you have.

You must not take any peanut or peanut containing food in your diet whilst taking PALFORZIA.

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.

**PALFORZIA does not treat the symptoms of peanut allergy and you must not take PALFORZIA during an allergic reaction.**

Your doctor will advise the best time to start treatment depending on any medical conditions that you have.

PALFORZIA contains the substance that patients with peanut allergy react to. Allergic reactions to PALFORZIA may occur during treatment. These reactions mostly occur during the first two hours after taking a PALFORZIA dose and are usually mild or moderate but occasionally can be severe.

Stop taking PALFORZIA and get medical treatment straight away if you have any of the following symptoms:

- Trouble breathing
- Throat tightness or feeling of fullness in throat
- 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 of any other breathing condition
- Heartburn, difficult swallowing, pain with swallowing, stomach pain or chest pain that does not go away or worsens

Certain conditions or factors can increase the likelihood of an allergic reaction. These include:

- Worsening of asthma
- Having an open sore or other damage to the lining of the mouth or the passage leading from the mouth to the stomach (oesophagus)
- Exercising
- Having a hot bath or shower
- Being very tired or missing sleep
- For women, having your period
- Taking certain pain medications such as aspirin or ibuprofen
- Drinking alcohol
- Being stressed
- Taking PALFORZIA on an empty stomach
- Having an illness such as a cold or flu or other viral infections

There are actions you should take to avoid some of these factors from affecting you. These factors include: exercise, having a hot bath or shower, drinking alcohol, or taking this medicine on an empty stomach. See the sections on ‘PALFORZIA with food, drink and alcohol’ and ‘Dosing instructions’ for advice on what to do about these.

For all other conditions or factors listed above, contact your doctor for advice if you experience allergic reactions during any of these.

Your doctor will prescribe adrenaline for you to self-inject, which you must have with you at all times in case you have a severe allergic reaction. Your doctor will tell you how to recognise an allergic reaction and teach you when and how to use the adrenaline. Talk to your doctor and read the adrenaline package leaflet if you have any questions about its use.

If you use adrenaline, do not take any further doses of PALFORZIA and seek emergency medical care immediately afterwards.

Desensitisation to peanut with PALFORZIA takes time. The ability to tolerate gradually increasing small amounts of peanut has been shown after completion of all up-dosing levels of PALFORZIA and after at least 3 months of maintenance therapy and this continues to improve over time.

You must take PALFORZIA every day to maintain the desensitisation it provides. Missing any doses can lead to an increased risk of allergic reactions.

PALFORZIA treatment may not work in all patients.

### **Children and adolescents**

PALFORZIA is intended for children and young people aged 4 to 17 years and those who become adults whilst on treatment.

Do not give this medicine to children aged less than 4 years because it is not known if PALFORZIA is safe and effective in this age group.

### **Other medicines and PALFORZIA**

Tell your doctor if you are taking, have recently taken, or might take any other medicines.

### **PALFORZIA with food, drink and alcohol**

PALFORZIA should not be mixed with liquid (e.g., water, milk, juice, soup, smoothie).

Do not drink alcohol 2 hours before and 2 hours after taking PALFORZIA as this may increase the likelihood of an allergic reaction.

### **Pregnancy, breast-feeding and fertility**

Do not start treatment with 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.

### **Driving and using machines**

PALFORZIA may have a small effect on your ability to drive, cycle or operate machinery. Exercise caution for 2 hours after taking a dose of PALFORZIA in case you have an allergic reaction which affects your ability to drive, cycle, or use machinery. Wait until all symptoms of such allergic reactions have gone away before driving, cycling, or using machinery.

## **3. How to take PALFORZIA**

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

PALFORZIA is prescribed by doctors who are experienced in the diagnosis and treatment of allergy and allergic reactions, including anaphylaxis.

## **How should I take PALFORZIA?**

### Dosing

There are 3 phases of treatment with PALFORZIA: initial dose escalation, up-dosing, and maintenance. You must complete these treatment phases in the order that your doctor has prescribed. During the initial dose escalation and up-dosing phases, the dose of PALFORZIA is increased in a precise way. During the maintenance phase, you take the same dose of PALFORZIA each day.

You should take PALFORZIA every day to maintain your level of desensitisation to peanuts.

Tell your doctor on the day of each clinic visit if you are feeling unwell or if you feel your asthma is less controlled.

### Initial dose escalation

You will be treated with the first doses (initial dose escalation) of PALFORZIA over about 4 to 5 hours in your doctor's clinic. On the first day you will be treated with 0.5 mg, 1 mg, 1.5 mg, 3 mg, and 6 mg of PALFORZIA.

### Up-dosing

If you tolerate the initial dose-escalation phase, you will be asked to return to your doctor's clinic on another day (usually the next day) to start the up-dosing phase.

There are 11 different dose levels of up-dosing, starting with PALFORZIA 3 mg (level 1) and increasing to PALFORZIA 300 mg (level 11).

The up-dosing levels are shown in the table below:

<b>Daily dose</b>	<b>Dose level</b>	<b>Presentation of dose</b>
3 mg	level 1	3 × 1 mg capsules (red)
6 mg	level 2	6 × 1 mg capsules (red)
12 mg	level 3	2 × 1 mg capsules (red) and 1 × 10 mg capsule (blue)
20 mg	level 4	1 × 20 mg capsule (white)
40 mg	level 5	2 × 20 mg capsules (white)
80 mg	level 6	4 × 20 mg capsules (white)
120 mg	level 7	1 × 20 mg capsule (white) and 1 × 100 mg capsule (red)
160 mg	level 8	3 × 20 mg capsules (white) and 1 × 100 mg capsule (red)
200 mg	level 9	2 × 100 mg capsules (red)
240 mg	level 10	2 × 20 mg capsules (white) and 2 × 100 mg capsules (red)
300 mg	level 11	1 × 300mg sachet

The first dose of each up-dosing level is given to you by your doctor in a clinic. If you tolerate the first dose of a new dose level, your doctor will ask you to continue to take that dose every day at home for about 2 weeks.

During the up-dosing phase, your doctor will see you about every 2 weeks to assess you for a new up-dosing level.

You must have completed all 11 up-dosing levels before you can start maintenance treatment. It will take at least 22 weeks to complete all up-dosing levels.

### Maintenance dosing

If you are able tolerate level 11 of the up-dosing phase, your doctor will ask you to continue taking PALFORZIA at a 300 mg dose every day as maintenance therapy.

### **Preparation for use**

PALFORZIA is available either in capsules or sachets. Empty the powder from PALFORZIA capsules or sachets.

Do not swallow PALFORZIA capsules.

Open the daily dose of PALFORZIA.

- To open a capsule gently pull the two ends of the capsule apart over a bowl with soft food and empty the powder into the bowl by rolling each half of the capsule between the finger and thumb. Tap the ends of each half capsule to make sure that all the powder is emptied.
- To open a sachet carefully cut or tear along the top along the line indicated. Tip the sachet upside down over a bowl with soft food and tap the sachet to make sure that all the powder is emptied.

Empty the full dose of PALFORZIA oral powder on to a small amount of soft food to which you are not allergic such as fruit puree, yogurt, or rice-pudding. Make sure you are not allergic to the food used for mixing.

The food used for mixing should be cool and no warmer than room temperature.

Mix well.

Use just enough food to mix with PALFORZIA so you can eat it all in a few spoonfuls to take the full dose.

Take PALFORZIA immediately after mixing. However, if needed, you can mix PALFORZIA with food and keep it in a refrigerator for up to 8 hours before taking. If it is not used within 8 hours, throw it away and prepare a new dose.

### **Handling instructions**

Do not breathe in PALFORZIA powder as this could cause breathing problems (worsening of asthma) or cause an allergic reaction.

Wash your hands immediately after handling PALFORZIA capsules or sachets.

When your doctor has told you that an up-dosing level is complete, you must dispose of all remaining capsules or sachets from that pack (see section 5) before starting on a new level. This includes any extra doses that are provided in each pack, if not used.

### **Dosing instructions**

Take PALFORZIA at about the same time every day with food, preferably as part of your evening meal. Do not take this medicine on an empty stomach.

Do not take PALFORZIA at home on the days that you visit your doctor for assessment as your doctor will give you PALFORZIA on these days.

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.

Do not take within 2 hours of bedtime.

Do not have a hot bath or shower just before or for 3 hours after taking PALFORZIA.

Do not exercise just before or for 3 hours after taking PALFORZIA.

If you have been exercising or have taken a hot bath or shower and are feeling hot, or you are sweating and your heart is beating fast, do not take PALFORZIA until you have cooled down and your heart rate (pulse) has returned to normal.

Do not take more than your individual total daily dose according to your current dose level of PALFORZIA in a single day.

### **If you take more PALFORZIA than you should**

Taking PALFORZIA at doses more than those recommended increases the risk of allergic reactions.

In the case of severe reactions such as difficulty swallowing, difficulty breathing, changes in your voice, or a feeling of fullness in the throat, treat the reaction with adrenaline self-injector as instructed by your doctor and then contact a doctor immediately.

### **If you forget to take PALFORZIA**

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

Missed doses of PALFORZIA may cause you to lose the peanut tolerance you have built up and increase your risk of allergic reactions.

If you miss your dose of PALFORZIA for 1 to 2 days in a row, take the next dose at your normal scheduled time the next day.

If you miss your dose of PALFORZIA for 3 days in a row or longer, stop taking PALFORZIA and contact your doctor for advice on how to start your treatment again.

### **If you stop taking PALFORZIA**

Stopping PALFORZIA may cause you to lose the peanut tolerance you have built up and increase your risk of allergic reactions.

If you have any further questions on the use of this medicine, ask your doctor.

## **4. Possible side effects**

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

### **Important side effects**

PALFORZIA can cause severe allergic reactions that may be life-threatening. If you get any of the following symptoms, stop taking PALFORZIA, treat the reaction according to any instructions previously provided by your doctor, and then contact a doctor **immediately**.

- Trouble breathing
- Throat tightness or 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

PALFORZIA can cause problems with the stomach and digestive system including eosinophilic oesophagitis. This is a condition that affects the passage between the mouth and the stomach and affects up to 1 in 1,000 people. Symptoms of eosinophilic oesophagitis can include:

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

If you have these symptoms persistently, contact a doctor.

### **Other side effects**

**Very common** (may affect up to 1 in 10 people)

- Throat tightness
- Vomiting
- Stomach discomfort or ache
- Feeling sick
- Allergic reactions (mild or moderate)
- Cough
- Sneezing
- Throat irritation
- Stomach pain
- Tingling of mouth or itching in and around the mouth
- Hives
- Itchy skin

**Common** (may affect up to 1 in 100 people)

- Difficulty breathing
- Allergic reactions (severe)
- Wheezing

Allergic reactions may affect different parts of the body as follows:

- Skin related: hives, flushing or itching of the skin, face swelling, rash
- Breathing related: difficulty breathing, wheezing, cough, throat tightness, runny nose, throat irritation
- Stomach related: stomach pain, feeling sick, vomiting

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme.

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store PALFORZIA**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister or sachet after EXP. The expiry date refers to the last day of that month.



Store below 25°C.

Do not use this medicine if you notice any hard lumps of powder that do not easily fall apart or if the powder is discoloured.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What PALFORZIA contains

The active substance is peanut protein from defatted powder of peanut (*Arachis hypogaea L.*) seed.

The other ingredients are:

#### PALFORZIA 10 mg, oral powder in capsules for opening

Partially pregelatinised maize starch, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate

### What PALFORZIA looks like and contents of the pack

White to beige oral powder in capsule for opening or sachet.

#### Initial dose escalation (see section 3)

Each carton contains 13 capsules in 5 single-dose blisters:

- 0.5 mg (1 × 0.5 mg capsule)
- 1 mg (1 × 1 mg capsule)
- 1.5 mg (1 × 0.5 mg capsule and 1 × 1 mg capsule)
- 3 mg (3 × 1 mg capsules)
- 6 mg (6 × 1 mg capsules)

#### Up-dosing phase (see section 3)

Name/Capsule or sachet strength	Pack contents by dose level (daily dose)
PALFORZIA 1 mg oral powder in capsules for opening	<b>Level 1 (3 mg daily):</b> 48 capsules in blisters 16 doses (each blister-well contains 3 capsules of 1 mg)  <b>Level 2 (6 mg daily):</b> 96 capsules in blisters 16 doses (each blister-well contains 6 capsules of 1 mg)
PALFORZIA 10 mg PALFORZIA 1 mg oral powder in capsules for opening	<b>Level 3 (12 mg daily):</b> 48 capsules in blisters 16 doses (each blister-well contains 1 capsule of 10 mg + 2 capsules of 1 mg)

<b>Name/Capsule or sachet strength</b>	<b>Pack contents by dose level (daily dose)</b>
PALFORZIA 20 mg oral powder in capsules for opening	<b>Level 4 (20 mg daily):</b> 16 capsules in blisters 16 doses (each blister-well contains 1 capsule of 20 mg)  <b>Level 5 (40 mg daily):</b> 32 capsules in blisters 16 doses (each blister-well contains 2 capsules of 20 mg)  <b>Level 6 (80 mg daily):</b> 64 capsules in blisters 16 doses (each blister-well contains 4 capsules of 20 mg)
PALFORZIA 100 mg oral powder in capsules for opening	<b>Level 9 (200 mg daily):</b> 32 capsules in blisters 16 doses (each blister-well contains 2 capsules of 100 mg)
PALFORZIA 100 mg PALFORZIA 20 mg oral powder in capsules for opening	<b>Level 7 (120 mg daily):</b> 32 capsules in blisters 16 doses (each blister-well contains 1 capsule of 100 mg + 1 capsule of 20 mg)  <b>Level 8 (160 mg daily):</b> 64 capsules in blisters 16 doses (each blister-well contains 1 capsule of 100 mg + 3 capsules of 20 mg)  <b>Level 10 (240 mg daily):</b> 64 capsules in blisters 16 doses (each blister-well contains 2 capsules of 100 mg + 2 capsules of 20 mg)
PALFORZIA 300 mg oral powder in sachet	<b>Level 11 (300 mg daily):</b> 15 sachets (300 mg sachet)

#### Maintenance dosing (see section 3)

Each carton contains 30 sachets of 300 mg.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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**This leaflet was last revised in February 2025.**