

Palforzia oral immunotherapy treatment for peanut allergy

This leaflet gives information about having Palforzia treatment for a peanut allergy, including how the treatment is given, as well as the benefits and risks. If you have any questions, please speak to a clinician caring for your child.

Palforzia is a peanut oral immunotherapy (POIT) treatment. It is not a cure, but it can help to reduce the severity of allergic reactions that can occur with accidental exposure to peanuts. It can also increase the amount of peanuts your child can tolerate before they have a reaction.

Peanut allergies in children

Peanut allergies affect about 1 in 50 children in the UK. Symptoms of a peanut allergy can vary depending on the severity of the allergy. Minor symptoms include skin reactions, oral discomfort like itching or tingling, and a runny nose, but more serious symptoms are called anaphylaxis.

Anaphylaxis is a term we use for a range of severe allergic symptoms which affect the airway, breathing and circulation. Symptoms can include:

- difficulty breathing
- coughing
- wheezing
- becoming dizzy
- feeling very drowsy (sleepy)

Severe allergic reactions need emergency medical treatment with adrenaline.

How Palforzia works

Palforzia includes all of the different components of the peanut protein that can trigger allergic reactions.

Palforzia is the first treatment that is licensed for peanut desensitisation in children. It is the only immunotherapy for a food allergy that is approved by NICE (National Institute for Health and Care Excellence).

'Desensitisation' is when we make you less sensitive to something. It works by gradually increasing your tolerance to peanuts by using oral immunotherapy (OIT).

OIT is a very structured way of exposing people with allergies to small amounts of the food they are allergic to and gradually increasing the amount over a long period of time. This helps the body to build up a tolerance to the food, and reduces the risk of an allergic reaction to an accidental exposure.

Benefits of taking Palforzia

This treatment increases the amount (dose) of peanut your child can tolerate and reduces the severity of a reaction if they are exposed to it. This can help to ease some of the anxiety of having to avoid peanuts or treat an allergic reaction, if your child is accidentally exposed to peanuts.

Side effects and risks of taking Palforzia

Most patients only have mild symptoms such as abdominal (tummy) pain, and some have no symptoms during their treatment at all. Some patients have more severe symptoms. Continued side effects might mean your child needs to step back to a lower dose. If the side effects are severe or continue, even with dose reductions, the treatment might need to be stopped completely. This decision can be made by you and your child, or the clinical team.

Our holistic approach to your child's care will make sure that any side effects are managed and your child's safety is maintained during their treatment.

The most common side effects of Palforzia are abdominal pain, throat irritation, itching, feeling sick (nausea), being sick (vomiting), and hives. These are usually mild and temporary but might mean that the child or their parent wants to stop treatment.

Serious side effects of Palforzia are less common but, if they do occur, it's usually within 2 hours of taking the dose. This is why we supervise their first doses and their first increased dose in hospital.

Severe reactions to Palforzia can include anaphylaxis. If your child has any symptoms of anaphylaxis after taking Palforzia, you should use their adrenaline auto-injector (EpiPen® or Jext®) and seek urgent medical attention. You must let us know as soon as possible if your child has had a reaction, as we might need to adjust their schedule or treatment dose. You should not give any more doses of Palforzia until you have spoken to us.

You and your child will be trained to recognise and treat allergic reactions at every up-dosing appointment.

Each time your child's dose is increased, they will take the first dose in hospital. This allows us see any reaction to it, and act quickly if there are any allergic symptoms.

If your child does not tolerate the increase in dose, they may need extra time at the previous dose level before trying an increase again. If there are no reactions, you will then give the same dose to your child at home until the next up-dosing appointment, which is usually 2 weeks later.

Please make sure you read the information leaflet that comes with the medicine, so that you are aware of all of the possible side effects.

There are some situations when Palforzia should not be taken as it might affect your child's immune response to the treatment. This will all be discussed with you before your child starts treatment.

Is Palforzia a cure for a peanut allergy?

The most important point to note is that **Palforzia is not a cure for peanut allergy**. However, it:

- increases the amount of peanut your child can eat before they react
- reduces the chance of a severe reaction
- makes any symptoms more likely to be mild

It is important for you to understand that your child may have more reactions while being on Palforzia OIT than by avoiding peanuts completely. This is because they will be exposed to peanuts every day.

If the treatment is successful, your child will have reached the maintenance dose. They will still have to avoid peanuts **for the rest of their life** and always carry their emergency medicines with them.

During Palforzia treatment

When you have agreed for your child to start Palforzia, you'll be offered a date to start. Please be aware we cannot change the start date once it has been agreed.

We will call you a week before your child starts treatment, to make sure they are well and that you have all the information. Palforzia treatment involves time commitment from the patient and their family. The treatment programme consists of 3 stages.

1 Dose escalation on the first 2 days of treatment

On the first day of Palforzia treatment, your child will be admitted for a full-day visit. We'll explain the treatment plan again, and you will need to sign a consent form. We also ask you and your child to complete a quality-of-life questionnaire. You and your child will return the next day to begin the first level of Palforzia. This appointment will take about 90 minutes.

The up-dosing stage, which lasts about 4 to 5 months

You and your child will need to return every 2 weeks, to increase the dose to the next level. This is called 'up-dosing'. These appointments continue until the maintenance dose of 300mg is reached.

These appointments will involve taking time off school (and work), and travelling to and from the hospital. The appointments usually last about 90 minutes. You'll need to bring the food you intend to mix the Palforzia into, every time you visit.

When your child has had the next dose level in hospital, they will need to take the dose at home, **every day** at about the same time.

If your child is not tolerating the treatment or is unwell, you must let us know as we might need to adjust the doses and arrange extra appointments.

2 A maintenance stage, which lasts up to 18 months

Your child must continue to take 300mg of Palforzia every day during the maintenance stage, to make sure they remain exposed to peanut protein.

We cannot change the appointment schedule unless your child is unwell and we need to adjust their treatment plan. If you have a holiday or commitment already booked, we might be able to extend the dose they are on so that an appointment can be missed.

3 After the maintenance stage is reached

After the maintenance stage, your child should be able to eat about 1.5 peanuts. They will need to have this amount of peanut **every day, for life**. This is to make sure that their tolerance of peanuts continues. Your child's immunity to peanuts will probably fade if exposure to them is stopped, even after they have completed the course of treatment. We will give you instructions about what to do when your child misses their daily peanut dose.

They will also need to continue to avoid peanuts, and carry their auto-injector device with them, at all times.

We will ask you and your child to complete the quality-of-life questionnaire again when your child moves (transitions) from Palforzia to real-peanut treatment. This is so that we can check that the treatment is helpful for you both, and we can use any results to improve our service. We will also repeat their skin prick test and blood tests to peanut.

How to take Palforzia

Palforzia is a powder that comes as capsules containing a dose of 0.5mg, 1mg, 10mg, 20mg, 100mg, and 300mg sachets. Your child will take the required number of capsules, or sachets to make up their prescribed treatment each day.

The capsules and sachets must be opened up and the powder mixed with a small amount of soft, cool food, like yoghurt, custard or rice pudding, and eaten after a meal. It should be taken every day, at about the same time.

The powder must be mixed well and fully coated by the food, with no chance of any product being left over at the end. Thoroughly coating Palforzia in the food also reduces the chance of any oral allergic symptoms.

- The capsules should not be swallowed whole.
- Palforzia should not be mixed into hot food.

There are 11 different dosing levels, which are taken every day for 2 weeks, over several months until the maintenance dose of 300mg is reached. You will be given very detailed instructions about how much your child should take.

There are a number of rules which you and your child will need to follow **every day** while on peanut immunotherapy.

For your child's safety, these rules need to be followed for life when on Palforzia and real peanuts, and will be reviewed at every appointment.

Do

- continue to follow a strict peanut-avoidance diet during the programme (except for the OIT doses)
- have the dose of Palforzia every day after food, and at about the same time
- monitor your child for any symptoms, for 1 hour after each dose
- tell us if your child has an allergic reaction
- make sure you have your child's emergency medicines and written plan for how to manage allergic reactions at all times

Do not

- do not swallow a capsule of Palforzia whole (the contents of the capsule must be mixed into soft, cool food)
- do not take a hot bath or shower right before, or for 3 hours after, taking peanut OIT
- do not do any exercise 1 hour before, or 3 hours after, each dose
- do not take the dose in the 2 hours before going to sleep

If your child is ill or misses doses

If your child is having a flare up of asthma (wheezy, tight chest, breathless or they need their reliever inhaler), or if there is a reaction to the Palforzia or any other food they are allergic to, miss that day's dose.

You must let us know if they react to the dose of Palforzia.

If your child is unwell, or misses 3 or more doses in a row, the treatment needs to be temporarily stopped. You will need to contact us to discuss when and how to restart the treatment.

Your child might need an extra appointment, and to have their next dose under supervision in the hospital.

It is important to take Palforzia every day as directed by the clinical team. Your child should not routinely miss any doses. If they do, you will need to speak to the clinical team for advice.

What could prevent your child from taking Palforzia?

Before starting Palforzia treatment, it is important to talk to the clinical team about your child's medical history, and tell them about any medicines your child is taking. This includes prescriptions and anything you might buy from a pharmacy, shop or online, and any herbal or homeopathic remedies.

It's important to tell your child's doctor if your child has:

- asthma
- eczema
- hay fever
- gastrointestinal conditions
- hives (urticaria)
- other allergies

If your child has any of these conditions, the treatment may not be suitable, so we might need to adjust the treatment plan or even stop the treatment. It is important that these conditions are well controlled while your child is taking Palforzia. If there is a flare up of other allergic conditions such as asthma, your child is more likely to react to their dose of Palforzia.

Certain medicines and activities need to be considered when taking Palforzia to reduce the risk of reactions. Non-steroidal anti-inflammatory medicines (NSAIDs), such as ibuprofen, can also change the way you react to Palforzia. You should take extra care when giving these to your child, and speak to the clinical team if your child needs to take ibuprofen.

Menstruation is another factor that can influence how you react to the medicine. If your child has allergic symptoms while on their period, tell the clinical team as they might need to adjust the doses.

Referral to the service and waiting times

Due to the number of patients currently waiting for this treatment, we are now **not accepting any more referrals** for Palforzia OIT.

There are only a few centres offering Palforzia in the UK, and other hospitals also have very limited places. They are usually only starting patients in their local catchment area who are already being seen by the allergy team.

There has been a huge demand for Palforzia since it became available. Although we want to treat as many people as possible, even if your child's name is already on our database, we might not be able to offer them a date to start treatment.

Our current waiting time is between 1 and 10 years, depending on when they were added to our database. Some families have chosen to start their child privately, which we are also able to offer. Please see our website for further details.

As this is a children's service, we need to have children ready to move on to having real peanuts before they can be discharged to adult services. This means **we do not start any child over the age of 15 years on Palforzia**.

When your child moves to adult services, they will need to be very familiar with their daily doses of real peanut, and the rules (the 'Do' and 'Don't' sections above). Their follow-up will be minimal, as we expect adult patients to manage their oral immunotherapy.

While your child is waiting to start, or is on Palforzia, their routine allergy care will still need to be provided by your local team

If your child is already on our database, you will be contacted and offered a pre-selection video call when your child's name nears the top of the list. Your child, no matter how young they are, must also attend the video appointment. You will be given 7 days, from the date of the video appointment, to decide if your child will proceed with Palforzia treatment.

If you decide that this treatment is not right for you or your child, please contact us via email as soon as possible so we can offer the place to another child.

Contact us

Email: gst-tr.allergypaediatrics@nhs.net

The allergy service is open Monday to Friday, 9am to 5pm.

Children's Allergy Day Unit (CADU), 2nd floor, Block D, South Wing, St Thomas' Hospital.
Otter outpatient department, 2nd floor, Block B, South Wing, St Thomas' Hospital.

For more information about conditions, procedures, treatments and services offered at our hospitals, please visit **web:** www.evelinalondon.nhs.uk/leaflets

Leaflet number: 5511/VER1

Date published: February 2025

Review date: February 2028

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A list of sources is available on request

