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Palforzia (*defatted powder of peanuts*)

An overview of Palforzia and why it is authorised in the EU

What is Palforzia and what is it used for?

Palforzia is a medicine for treating peanut allergy in children from 4 to 17 years of age and patients who become adults whilst on treatment. While taking this medicine, patients continue avoiding peanuts.

Palforzia contains peanut powder.

How is Palforzia used?

Palforzia is available as a powder in capsules or sachets. The patient opens the capsules or sachets and mixes the powder with a small amount of soft food (such as like fruit puree, yogurt and rice pudding).

In the first phase of treatment, which takes place in the clinic, the patient receives increasing doses of Palforzia over several hours on a single day under observation of the doctor. For the second phase, the doctor prescribes increasing doses each of which the patient should take daily for two weeks if they can tolerate it. This phase of increasing doses under supervision lasts at least 22 weeks. If the patient continues to tolerate treatment, in the third phase they will then be prescribed a daily dose to maintain the effects of the medicine.

Palforzia can only be obtained with a prescription. Treatment should be started by a healthcare professional qualified to treat allergic diseases. Because this medicine can cause serious allergic reactions in some patients, for the first phase of treatment, facilities must be on hand for treating such reactions. The patients should also have self-injectable adrenaline with them at all times.

For more information about using Palforzia, see the package leaflet or contact your doctor or pharmacist.

How does Palforzia work?

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. It is not effective against other nut or food allergies.

Palforzia does not treat the symptoms of peanut allergy and must not be taken during an allergic reaction.

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What benefits of Palforzia have been shown in studies?

Two main studies involving 671 patients have shown that Palforzia can help some patients tolerate a small amount of peanuts with only mild symptoms.

In one of the studies, 50% of the patients aged 4 to 17 who took Palforzia could tolerate 1000 mg of peanut protein with only mild symptoms, compared with 2% of those who received placebo (a dummy treatment). In the second study, 58% of 4- to 17-year-olds could tolerate the same dose of peanut protein with only mild symptoms compared with 2% of those who took placebo.

What are the risks associated with Palforzia?

The most common side effects with Palforzia (which may affect more than 1 in 5 people) are abdominal (belly) pain and discomfort, irritation in the throat and mouth, itchy skin, nausea, vomiting and urticaria (itchy rash).

Palforzia should not be taken by patients with severe or uncontrolled asthma or those who have ever had problems with swallowing or stomach acid or severe mast cell disorder (a condition that causes allergic-like reactions). It should also not be taken by patients who have had a severe allergic reaction in the past two months.

For the full list of restrictions and side effects of Palforzia, see the package leaflet.

Why is Palforzia authorised in the EU?

Studies show that Palforzia can help young patients (aged 4 to 17) with peanut allergy to tolerate peanut protein with only mild symptoms. Although there are insufficient data from patients who become adults while on treatment, these patients should be able to decide with their doctor whether or not to continue treatment.

The side effects of Palforzia, including allergic reactions, can be managed by following advice for patients and healthcare professionals in the product information. The European Medicines Agency therefore concluded that Palforzia's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Palforzia?

The company that markets Palforzia will provide patients, healthcare professionals and caregivers with information about how to take the medicine and manage its risks. Patients will also receive a patient card which they should carry at all times.

Recommendations and precautions for the safe and effective use of Palforzia have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Palforzia are continuously monitored. Side effects reported with Palforzia are carefully evaluated and any necessary action taken to protect patients.

Other information about Palforzia

Palforzia received a marketing authorisation valid throughout the EU on 17 December 2020.

Further information on Palforzia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/palforzia

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