swissmedic

Summary report on authorisation dated 24 October 2025

Palforzia® (active substance: peanut allergens (Arachis hypogaea))

Indication extension in Switzerland: 25 February 2025

Powder for treatment of patients aged 1 to 17 years with confirmed peanut allergy

About the medicinal product

Palforzia contains protein obtained from peanuts (Arachis hypogaea) and is administered as a powder to be taken orally.

Palforzia was first authorised by Swissmedic on 4 May 2021 for the treatment of children and adolescents aged 4 to 17 years with confirmed peanut allergy, including adolescents who reach adulthood whilst on treatment.

This indication extension means that from 25 February 2025, Palforzia is now also authorised for infants aged 1 to 3 years with confirmed peanut allergy.

Mode of action

Palforzia is a powder with peanut proteins and contains allergens that cause reactions in patients with a peanut allergy.

The initial dose of peanut allergens during Palforzia treatment is usually low enough to avoid triggering or only trigger a minor allergic reaction. By slowly escalating the dose, the peanut quantity that can be tolerated is gradually increased without triggering a severe allergic reaction.

Due to its peanut allergens, Palforzia can itself also trigger allergic reactions in patients, particularly if the dosage is increased too rapidly.

Administration

Palforzia is a prescription-only powder to be taken orally. Before taking, it is mixed with a soft food (e.g. apple purée or yoghurt) to which the patient is not allergic. Strict adherence to the instructions and the dosage schedule is important in order to avoid dangerous allergic reactions. Treatment with Palforzia is administered in 3 phases: initial dose escalation, up-dosing, and maintenance.

Initial dose escalation takes place on a single day and for infants aged 1 to 3 years includes 4 increasing dosage levels, while for older

children and adolescents aged 4 to 17 years, there is an additional, higher dosage level.

The subsequent up-dosing spans several weeks, over which the daily quantity is gradually increased. In infants aged 1 to 3 years, this phase begins with an additional, lower initial dose. Each new dosage increase takes place under medical supervision. A dose can be considered to be tolerated when no more than temporary mild symptoms are observed and no medical intervention/therapy is necessary.

In the maintenance phase, the medicinal product is taken at a consistent dose of 300 mg daily by all patients aged 1 to 17 years in order to maintain the therapeutic effect.

During treatment with Palforzia, peanuts or foods containing peanuts must continue to be avoided.

Efficacy

The efficacy of Palforzia has been investigated in several randomised (randomly assigned), placebo-controlled Phase 3 studies[1].

The PALISADE and ARTEMIS studies were carried out in children and adolescents aged 4 to 17 years. The results showed that more than half (PALISADE 50.3% versus 2.4%, ARTEMIS 58.3% versus 2.3%) of the children treated with Palforzia tolerated a single 1000 mg dose of peanut protein (equivalent to approximately 3 peanuts). In comparison, less than 3% of the placebo group tolerated this quantity.

The POSEIDON study also assessed the efficacy of Palforzia in children aged 1 to 3 years. Here, 68.4% of the children treated with Palforzia tolerated a single 1000 mg dose of peanut protein, compared with 4.3% in the placebo group.

The described treatment benefit must be weighed against potential allergic reactions to Palforzia. Overall, the studies showed that severe allergic reactions occurred more frequently with Palforzia treatment than with placebo. However, the majority of these cases were mild to moderate. The available data indicate that the risk of a systemic allergic reaction in adolescents (22.5%) is higher than that in children (≤11 years; 12.5%). In children aged 1 to 3 years, 11 subjects (11.2%) in the Palforzia group and 2 subjects (4.2%) in the placebo group had at least 1 episode with adrenaline administration.

Precautions, undesirable effects, & risks

The quantity of peanut protein tolerated without an allergic reaction can be increased significantly in the course of treatment with Palforzia. However, allergic reactions may occur not only at the start of treatment but also after prolonged use. These range from mild symptoms such as reddening of the skin or itching to severe reactions that may be life-threatening.

The most common undesirable effects of Palforzia in patients aged 1 to 17 years include gastrointestinal symptoms[2], skin reactions, and respiratory diseases. Certain undesirable effects such as cough, hives[3], or vomiting occur more frequently in infants aged 1 to 3 years than in older children and adolescents (4 to 17 years) taking Palforzia, although

[1] Placebo-controlled Phase 3 study: Advanced clinical study in which a medicinal product is compared with a dummy treatment (placebo) in order to check its effectiveness and safety before authorisation.

[2] Gastrointestinal symptoms: Symptoms involving the stomach and intestines, such as stomach pain, nausea, or vomiting.

[3] Hives: A skin reaction in which red, itchy areas of skin or bumps (wheals) suddenly appear; these often disappear again quickly and reappear in other places.

these symptoms could in principle occur in all tested age groups (1 to 17 years).

Severe symptoms require immediate treatment, including administration of adrenaline and subsequent medical evaluation. Patients who receive Palforzia must therefore be trained in how to recognise allergic reactions at an early stage and how to act correctly in an emergency. It is vital that an emergency kit containing injectable adrenaline is available at all times.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The POSEIDON study proved that the benefit of treatment with Palforzia in infants aged 1 to 3 years is comparable with the benefit in children and adolescents aged 4 to 17 years, with tolerance in terms of severe allergic reactions in infants aged 1 to 3 years appearing to be better than that in older children/adolescents in the historic comparison of the studies. Treatment with Palforzia can significantly increase the tolerated peanut quantity in this younger age group, too.

Based on all the available data, the benefits of indication extension outweigh the risks. Swissmedic has therefore approved the indication extension of Palforzia in Switzerland for the treatment of patients aged 1 to 3 years with confirmed peanut allergy.

Further information on the medicinal product

Information for healthcare professionals:

Information for healthcare professionals Palforzia®

Information for patients (package leaflet):
Information for patients Palforzia®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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