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

First authorisation in Switzerland: 4 May 2021

Medicinal product (powder) for the treatment of patients with confirmed peanut allergy

About the medicinal product

Palforzia contains proteins obtained from peanuts (Arachis hypogaea).
Palforzia is indicated for the treatment of patients with confirmed peanut allergy. It is used to increase the peanut quantity that can be ingested without triggering an allergic reaction.

Palforzia is intended for children and adolescents aged 4 to 17 years and for those who reach adulthood whilst on treatment. Patients can continue to receive the treatment after the age of 18.

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 during Palforzia treatment is usually low enough to avoid triggering an allergic reaction. By slowly escalating the dose, the peanut quantity that can be tolerated is gradually increased (up to 3 peanuts). However, Palforzia can also trigger allergic reactions in patients with a peanut allergy, particularly if the dosage is increased too rapidly.

Use

Palforzia is available only on prescription. 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. These administration phases must proceed in the sequence specified by the doctor. During the initial escalation and up-dosing phases, Palforzia is taken in precise, increasing doses. During the maintenance phase, the same Palforzia dose is taken every day.

In order to maintain the therapeutic effect, Palforzia must be taken every day. If the

treatment with Palforzia is interrupted for more than 14 days, an up-dosing process lasting several months must be implemented on resumption of treatment, regardless of the preceding duration of treatment.

Palforzia is taken as a powder mixed with a soft food, such as apple purée, yogurt, rice pudding or other food to which the patient is not allergic.

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

Palforzia is available in capsules or sachets in various dosages ranging from 0.5 mg to 300 mg. The oral powder must be emptied out of the capsules or sachets before mixing it with food.

Efficacy

The efficacy of Palforzia was evaluated on the basis of the completed PALISADE and ARTEMIS studies, as well as the RAMSES study, which is continuing after authorisation.

In the three studies, 841 patients have been treated with Palforzia and compared with 335 patients who received a placebo (dummy drug).

The data from the studies show that the tolerated peanut quantity could be increased to 1,000 mg (corresponding to about 3 peanuts) in over half of the children aged from 4-17 with severe peanut allergy who received the recommended treatment with Palforzia. By contrast, over 90% of the children treated with placebo were unable to tolerate peanut doses above 100 mg.

Allergic reactions thought to be triggered by food (including those triggered specifically by peanuts) were proportionally less frequent during the treatment with Palforzia compared to the treatment with placebo (171 allergic reactions in 841 patients versus 117 reactions in 335 patients). The difference was even more pronounced for events triggered by peanuts (47/841 versus 39/335).

The described benefit of the treatment is contrasted with allergic reactions to Palforzia. Overall, more severe allergic reactions (136 in 841 patients) were reported for the treatment with Palforzia than for the treatment with placebo (15 in 335 patients). Most of the severe allergic reactions to Palforzia occurred within 2 hours of administration of the treatment. Such reactions can be easier to manage than the almost unpredictable severe reactions caused by accidental peanut exposure.

Precautions, undesirable effects & risks

The peanut quantity that can be tolerated without triggering an allergic reaction is increased during the course of treatment with Palforzia. Nevertheless, allergic reactions to Palforzia can still occur, not just at the start of treatment but also after a prolonged period of treatment. Such reactions can be severe or, in rare cases, even life-threatening. Severe reactions such as difficulty swallowing, difficulty breathing, changes in voice or a feeling of fullness in the throat, require immediate treatment, including the use of adrenaline and subsequent medical evaluation. Patients who receive Palforzia must therefore be taught to recognise the signs and symptoms of allergic reactions, and they should also carry self-injectable adrenaline at all times.

All precautions, risks and other possible undesirable effects will be listed in the Information for patients (package leaflet) and the Information for healthcare professionals. These will be available as soon as the product is available in Switzerland.

Why the medicinal product has been authorised

The demonstrated benefit of the treatment with Palforzia in patients aged from 4-17 was the ability to increase the tolerated peanut quantity during the treatment period. In order to maintain the increased peanut tolerability, Palforzia must be taken every day.

The frequency of allergic reactions in the submitted studies was higher overall during the treatment with Palforzia than during the administration of placebo. However, the reactions triggered by Palforzia were easier to predict than reactions caused by accidental peanut exposure, which can be beneficial particularly for patients with a severe peanut allergy.

Based on all the available data, the benefits of Palforzia outweigh the risks. Swissmedic has therefore authorised the medicinal product Palforzia with protein powder from peanuts (Arachis hypogaea) for use in Switzerland.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Palforzia, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals (doctors, pharmacists and others) can answer any questions about this medicine.

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 Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.