

14 November 2024
EMA/CHMP/397782/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Palforzia

defatted powder of *Arachis hypogaea* L., semen (peanuts)

On 14 November 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Palforzia. The marketing authorisation holder for this medicinal product is Stallergenes.

The CHMP adopted an extension to the existing indication to include treatment of children from 1 year of age, as follows:²

PALFORZIA is indicated for the treatment of patients aged **41** to 17 years with a confirmed diagnosis of peanut allergy. PALFORZIA may be continued in patients 18 years of age and older.

PALFORZIA should be used in conjunction with a peanut-avoidant diet.

For information, the full indication for Palforzia will be as follows:

PALFORZIA is indicated for the treatment of patients aged 1 to 17 years with a confirmed diagnosis of peanut allergy. PALFORZIA may be continued in patients 18 years of age and older.

PALFORZIA should be used in conjunction with a peanut-avoidant diet.

The CHMP also adopted two new contraindications, as follows:

- A history of food protein-induced enterocolitis syndrome (FPIES) in the past 12 months (applicable for patients aged 1-3 years, see section 5.1)
- A history of failure to thrive (applicable for patients aged 1-3 years, see section 5.1)

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold, removed text as strikethrough