



Questions to the Committee

Questions to the Committee



Q1. Are the available efficacy data adequate to support the use of Palforzia as a treatment to reduce the incidence and severity of allergic reactions, including anaphylaxis, after accidental exposure to peanut in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

Please vote yes or no

Questions to the Committee

As part of a Risk Evaluation and Mitigation Strategy, the Agency will require the following to mitigate the risk(s) of systemic allergic reactions, including anaphylaxis, due to Palforzia:

- a. Documentation that any patient prescribed Palforzia has a valid prescription for injectable epinephrine.**
- b. Caregivers/patients must attest to carrying injectable epinephrine while on Palforzia.**
- c. Initial dose escalation and the first dose of each up-dosing level must be administered in a certified facility capable of treating systemic allergic reactions.**

Q2. Are the available safety data, in conjunction with these additional safeguards, adequate to support the use of Palforzia in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

Please vote yes or no