



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2026
EMADOC-1829012207-50265
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Vijoice alpelisib

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Vijoice², intended for the treatment of adults and children aged 2 years and older with severe or life-threatening manifestations of PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy.

The applicant for this medicinal product is Novartis Europharm Limited.

Vijoice will be available as 50 mg, 125 mg and 200 mg film-coated tablets, and 50 mg granules. The active substance of Vijoice is alpelisib, an antineoplastic agent, phosphatidylinositol-3-kinase (PI3K) inhibitor (ATC code: L01EM03). Alpelisib blocks the activity of the PI3K enzyme, thereby reducing the abnormal growth of tissues.

The benefits of Vijoice are based on the results of a main study which involved the retrospective review of medical records from 57 patients aged 2 years and older who received alpelisib through a compassionate use programme. The patients had severe or life-threatening symptoms of PROS that required systemic treatment. The main measure of effectiveness was the number of patients who, after 24 weeks of treatment, had at least a 20% reduction in the size of 1 to 3 abnormal growths or tumours, assessed mainly using imaging scans. Of the 32 patients who had a response assessment at 24 weeks, 37.5% (12 out of 32) responded to treatment with Vijoice. In addition, a follow-up study involving patients who had taken part in the compassionate use program provided further supportive evidence about the medicine's safety and efficacy.

The most common side effects with Vijoice include hyperglycaemia, diarrhoea, headache, stomatitis, alopecia, dermatitis, dry skin and nausea.

The full indication is:

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 This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained.



Vijoice is indicated for the treatment of adult and paediatric patients aged 2 years and older with severe or life-threatening manifestations of PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy.

Treatment with Vijoice should be initiated by a physician with experience in the management of PROS.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.