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Vijoice (*alpelisib*)

A plain-language overview of Vijoice and why it is authorised in the EU

What is Vijoice and what is it used for?

Vijoice is used to treat severe or life-threatening PIK3CA-related overgrowth spectrum (PROS) disorders in adults and children aged two years and older who need systemic (whole-body) treatment.

PROS is a diverse group of rare genetic conditions causing uncontrolled growth of some tissues in the body, leading to malformations and lesions affecting the skin, bones, soft tissue, blood vessels and brain.

PROS is rare, and Vijoice was designated an 'orphan medicine' (a medicine used in rare diseases) on 26 March 2021. Further information on the orphan designation can be found on the EMA website.

Vijoice contains the active substance alpelisib.

How is Vijoice used?

Treatment should be started by a doctor experienced in managing patients with PROS.

Vijoice is available as tablets and granules to be taken by mouth. It is taken once a day, immediately after food, at about the same time each day. Patients who are not able to swallow tablets may crush the tablet in water as instructed in the package leaflet. Treatment continues for as long as the patient's condition does not worsen or they do not have unacceptable side effects.

The medicine can only be obtained with a prescription. For more information about using Vijoice, see the package leaflet or contact your doctor or pharmacist.

How does Vijoice work?

PROS is caused by mutations in a gene called PIK3CA, which lead to the production of an abnormal form of an enzyme called PI3 kinase that is involved in cell growth. This abnormal form of PI3 kinase causes the overgrowth of affected tissues and malformations seen in people with PROS.

The active substance in Vijoice, alpelisib, is a PI3 kinase inhibitor that works by blocking the activity of the enzyme, thereby reducing the abnormal growth of tissues.

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What benefits of Vijoice have been shown in studies?

A main study, involving a review of medical records of patients aged two years and older, showed that treatment with Vijoice reduced the size of abnormal tissue overgrowth.

The patients had severe or life-threatening symptoms of PROS that required systemic treatment and the study looked at the number of patients who, after 24 weeks of treatment, had a reduction of at least 20% in the size of 1 to 3 abnormal growths or lesions. Of the 32 patients who had an assessment at 24 weeks, 37.5% (12 out of 32) responded to treatment with Vijoice.

Studies carried out with Vijoice are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Vijoice?

For the full list of side effects and restrictions with Vijoice, see the package leaflet.

The most common side effects with Vijoice (which may affect more than 1 in 10 people) include hyperglycaemia (high blood glucose levels), decreased appetite, diarrhoea, vomiting, headache, stomatitis (inflammation of the lining of the mouth), nausea (feeling sick), abdominal (belly) pain, rash, dermatitis (inflammation of the skin), dry skin, hair loss, low levels of phosphate and calcium in the blood, high levels of creatinine, glucose, glycosylated haemoglobin and lipase (an enzyme that breaks down fats) in the blood.

Some side effects can be serious. The most frequent in adults (which may affect up to 1 in 10 people) include dehydration and hyperglycaemia, and in children the most frequent (also affecting up to 1 in 10 people) were diarrhoea, headache and rash.

Why is Vijoice authorised in the EU?

Before the authorisation of Vijoice, no other medicine was authorised for PROS and treatment consisted of supportive care, including surgery and procedures to block overgrown blood vessels.

A review of medical records showed that treatment with Vijoice reduced the size of abnormal tissue overgrowths. The side effects seen with Vijoice can be managed with appropriate monitoring and treatment.

Vijoice has been given conditional authorisation for use in the EU. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Vijoice. In order to further confirm the benefits and safety of alpelisib, the company must submit the final results of an ongoing study involving adults and children with PROS. Every year, the Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Vijoice?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Vijoice have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Vijoice are continuously monitored. Suspected side effects reported with Vijoice are carefully evaluated and any necessary action is taken to protect patients.

Other information about Vijoice

Vijoice received a conditional marketing authorisation valid throughout the EU on 15/07/2026.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 07-2026.