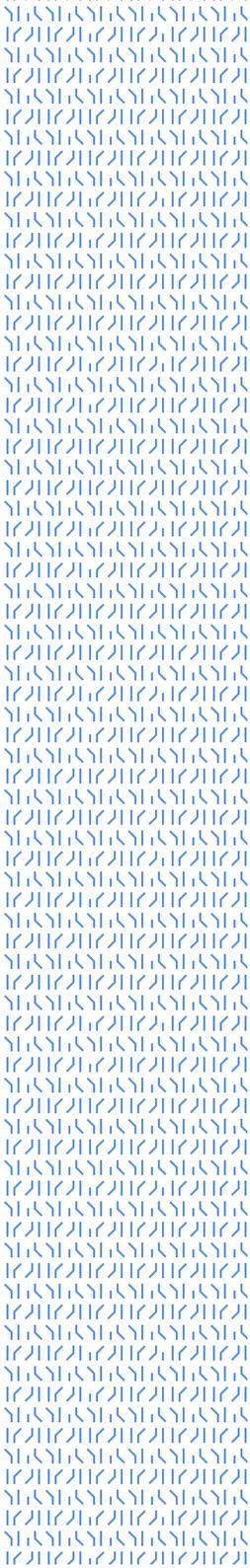


## Vioice® (alpelisib)



# About Vioice® (alpelisib) tablets

Vioice is the first and only FDA-approved treatment for select patients with PIK3CA-Related Overgrowth Spectrum (PROS) conditions.

## What is Vioice?

Vioice® (alpelisib) is a prescription medicine used to treat adults and children 2 years of age and older with severe phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA)-Related Overgrowth Spectrum (PROS). It is not known if Vioice is safe and effective in children below 2 years of age. Vioice is not approved in any other country or region.

## PIK3CA Mutations and PROS



**PROS is caused by a mutation in the PIK3CA gene.** The PIK3CA gene provides instructions for developing proteins and enzymes in the body, including in the phosphatidylinositol 3-kinase (PI3K) pathway.<sup>1</sup> Somatic, or non-inherited, mutations in the PIK3CA gene can result in hyperactivation of the PI3K protein, which leads to increased cellular proliferation and abnormal growth of affected tissue.<sup>1</sup>



**PIK3CA mutations may be present at various levels in different cells.** For people living with PROS conditions, mutations occur during embryonic development, resulting in a mosaic overgrowth pattern, or patches of affected and unaffected areas.<sup>2</sup> As a result of these mutations, PROS conditions are characterized by tissue overgrowths and blood vessel anomalies.<sup>3,4</sup>



**Diagnosing PROS may require several steps.** PROS conditions often can be diagnosed through medical history, a physical exam, and/or imaging.<sup>2,5</sup> There are tests to detect the presence of a PIK3CA mutation, but a presumptive PROS diagnosis may be made based on features if no mutation is identified because the mutations can be difficult to detect.<sup>2</sup>

## How Does Vioice Work?

Vioice is a PI3K inhibitor. By inhibiting the PI3K pathway, Vioice addresses the effects of PIK3CA mutations.<sup>1</sup> Vioice can also affect healthy cells. How Vioice works has only been demonstrated in laboratory studies.

## Dosing & Administration

The recommended dose of Vioice in adult patients is 250 mg (one 200 mg film-coated tablet and one 50 mg film-coated tablet) taken orally, once daily, with food.

The recommended dose in pediatric patients is 50 mg (one 50 mg film-coated tablet) taken orally, once daily, with food. Patients should take their dose of Vioice at approximately the same time each day.

## Important Safety Information

Patients should not take VIJOICE if they have had a severe allergic reaction to alpelisib or are allergic to any of the ingredients in VIJOICE.

**Please see additional Important Safety Information on the following page and [click here for full Prescribing Information.](#)**

## Important Safety Information (continued)

VIJOICE may cause serious side effects. VIJOICE can cause severe allergic reactions. Patients should tell their health care provider or get medical help right away if they have trouble breathing, flushing, rash, fever, or fast heart rate during treatment with VIJOICE. VIJOICE can cause severe skin reactions. Patients should tell their health care provider or get medical help right away if they get a severe rash or a rash that keeps getting worse; reddened skin; flu-like symptoms; blistering of the lips, eyes, or mouth; blisters on the skin or peeling skin, with or without a fever. VIJOICE can cause high blood sugar levels (hyperglycemia). Hyperglycemia is common with VIJOICE and can be severe. Health care providers will monitor blood sugar levels before patients start, and during treatment with, VIJOICE. Health care providers may monitor blood sugar levels more often if patients have a history of type 2 diabetes. Patients should tell their health care provider right away if they develop symptoms of hyperglycemia or its complications, including excessive thirst, dry mouth, urinating more often than usual or having a higher amount of urine than normal, increased appetite with weight loss, confusion, nausea, vomiting, fruity odor on breath, difficulty breathing, or dry or flushed skin. VIJOICE can cause lung problems (pneumonitis). Patients should tell their health care provider right away if they develop new or worsening symptoms of lung problems, including shortness of breath or trouble breathing, cough, or chest pain. Diarrhea is common with VIJOICE and can be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney injury. Patients who develop diarrhea during treatment with VIJOICE should tell their health care provider right away.

Before taking VIJOICE, patients should tell their health care provider if they have a history of diabetes; skin rash; redness of skin; blistering of the lips, eyes, or mouth; peeling skin; are pregnant, or plan to become pregnant, because VIJOICE can harm their unborn baby. Females who can become pregnant should use effective birth control during treatment with VIJOICE and for 1 week after the last dose. Do not breastfeed during treatment with VIJOICE and for 1 week after the last dose. Males with female partners who can become pregnant should use condoms and effective birth control during treatment with VIJOICE and for 1 week after the last dose.

Patients should tell their health care provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VIJOICE and other medicines may affect each other and cause side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

The most common side effects of VIJOICE are diarrhea, mouth sores (stomatitis), and hyperglycemia.

**Please see full Prescribing Information for VIJOICE [here](#).**

### References

1. VIJOICE: Prescribing Information. East Hanover, New Jersey, USA: Novartis Pharmaceuticals Corporation; April 2022.
2. Keppler-Noreuil KM, Rios JJ, Parker VER, et al. PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation. *Am J Med Genet A*. 2015;167A(2):287-295.
3. Keppler-Noreuil KM, Sapp JC, Lindhurst MJ, et al. Clinical delineation and natural history of the PIK3CA-related overgrowth spectrum. *Am J Med Genet A*. 2014;164A(7):1713-1733.
4. Ko JM. Genetic syndromes associated with overgrowth in childhood. *Ann Pediatr Endocrinol Metab*. 2013;18(3):101-105.
5. Mirzaa GM, Riviere JB, Dobyns WB. 2013. Megalencephaly Syndromes and Activating Mutations in PI3K-AKT Pathway. *Am J Med Genet* 163:122-130.

