Pharmacy Reference for VIJOICE

Indication

VIJOICE® (alpelisib) tablets is indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.

This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

VIJOICE is the first and only FDA-approved treatment for pediatric and adult patients with PROS

Dosage and administration

VIJOICE is taken orally, once daily, with food, and at approximately the same time every day.

Recommended initial dose:

Pediatric patients (ages 2 to <18 years)
50 mg once daily

Adult patients
250 mg once daily

Dose reduction back to 50 mg may be required if ARs occur.

Discontinue VIJOICE in pediatric patients who cannot tolerate 50 mg daily.

Additional information:

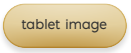
If a dose of VIJOICE is missed, it can be taken with food within 9 hours after the time it is usually taken. After more than 9 hours, skip the dose for that day. The next day, VIJOICE should be taken at the usual time.

If the patient vomits after taking the dose, advise the patient not to take an additional dose on that day and to resume the dosing schedule the next day at the usual time.

Patients should swallow VIJOICE tablets whole. Tablets should not be crushed, chewed, or split prior to swallowing. For patients who are not able to swallow tablets, or who are using a feeding tube, prepare and administer VIJOICE as a suspension and take with food. Do not use VIJOICE tablets that are broken, cracked, or damaged.

How supplied/storage and handling

VIJOICE is supplied as 50-mg, 125-mg, and 200-mg film-coated tablets and as a 50-mg packet of oral granules.

Daily dose	Each carton contains	Each blister pack or single-use packet contains	NDC
 250-mg daily dose	 **Two** 14-day supply blister packs (56 tablets total)	14 tablets: 200 mg alpelisib per tablet and 14 tablets: 50 mg alpelisib per tablet	0078-1035-02
 125-mg daily dose	 **One** 28-day supply blister pack	28 tablets: 125 mg alpelisib per tablet	0078-1028-84
 50-mg daily dose	 **One** 28-day supply blister pack	28 tablets: 50 mg alpelisib per tablet	0078-1021-84
 50-mg daily dose	 28 packets (28-day supply of single-use packets)	50 mg alpelisib	0078-1175-51

- Store at 20 °C to 25 °C (68 °F to 77 °F), excursions permitted between 15 °C and 30 °C (59 °F and 86 °F)

AR, adverse reaction; FDA, US Food and Drug Administration; NDC, National Drug Code.
Tablet, granules, and carton images are for illustrative purposes only.

Specialty pharmacy and distribution

Specialty Pharmacy:

1 exclusive national specialty pharmacy

Biologics

Phone: 1-800-850-4306
Fax: 1-800-823-4506

Distributors:

All orders must be placed with a distributor listed below:

ASD Healthcare | Cardinal Health | McKesson Specialty Health

Hospital outpatient pharmacies or outpatient clinic/practice pharmacies are also approved to dispense VIJOICE.

Important Safety Information

VIJOICE is contraindicated in patients with severe hypersensitivity to alpelisib or any of its ingredients.

Please see the following page for additional Important Safety Information.
Please click here for full Prescribing Information.

Vijoice® (alpelisib) tablets
50 mg | 125 mg | 200 mg

Important Safety Information (cont)

Severe Hypersensitivity. Severe hypersensitivity reactions, including anaphylaxis, angioedema, and anaphylactic shock, have occurred in adult patients treated with alpelisib in the oncology setting and in patients treated with VIJOICE. VIJOICE is not approved for use in the oncology setting. Permanently discontinue VIJOICE in the event of severe hypersensitivity.

Severe Cutaneous Adverse Reactions (SCARs). SCARs, including Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), have occurred in adult patients treated with alpelisib in the oncology setting and may occur in patients treated with VIJOICE. If signs or symptoms of SCARs occur, interrupt VIJOICE until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, permanently discontinue VIJOICE. If a SCAR is not confirmed, VIJOICE may require dose modifications, topical or systemic corticosteroids, or oral antihistamine treatment.

Hyperglycemia. Severe hyperglycemia, in some cases associated with hyperglycemic hyperosmolar nonketotic syndrome (HHNKS) or fatal cases of ketoacidosis, has occurred in adult patients treated with alpelisib in the oncology setting and may occur in patients treated with VIJOICE.

In the EPIK-P1 study, grade 1 or 2 hyperglycemia was reported in 12% of patients treated with VIJOICE.

Before initiating treatment with VIJOICE, test fasting plasma glucose (FPG), HbA1c, and optimize blood glucose. After initiating treatment with VIJOICE, monitor fasting glucose (FPG or fasting blood glucose) at least once every week for the first 2 weeks, then at least once every 4 weeks, and as clinically indicated. Monitor HbA1c every 3 months and as clinically indicated. Monitor fasting glucose more frequently for the first few weeks during treatment with VIJOICE in patients with risk factors for hyperglycemia, such as obesity (body mass index ≥30), elevated FPG, HbA1c at the upper limit of normal or above, use of concomitant systemic corticosteroids, or age ≥75.

If a patient experiences hyperglycemia after initiating treatment with VIJOICE, monitor fasting glucose as clinically indicated and at least twice weekly until fasting glucose decreases to normal levels. During treatment with antihyperglycemic medication, continue monitoring fasting glucose at least once a week for 8 weeks, followed by once every 2 weeks, and as clinically indicated. Consider consultation with a health care provider with expertise in the treatment of hyperglycemia, and counsel patients on lifestyle changes.

The safety of VIJOICE in patients with type 1 and uncontrolled type 2 diabetes has not been established. Patients with a history of diabetes mellitus may require intensified hyperglycemic treatment. Closely monitor patients with diabetes.

Interrupt, reduce the dose of, or permanently discontinue VIJOICE based on severity.

Pneumonitis. Severe pneumonitis, including acute interstitial pneumonitis and interstitial lung disease, has occurred in adult patients treated with alpelisib in the oncology setting and may occur in patients treated with VIJOICE.

In patients who have new or worsening respiratory symptoms or are suspected to have developed pneumonitis, interrupt VIJOICE immediately and evaluate the patient for pneumonitis. Consider a diagnosis of noninfectious pneumonitis in patients presenting with nonspecific respiratory signs and symptoms, such as hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic examinations and in whom infectious, neoplastic, and other causes have been excluded by means of appropriate investigations.

Permanently discontinue VIJOICE in all patients with confirmed pneumonitis.

Diarrhea and Colitis. Severe diarrhea, resulting in dehydration, and, in some cases, acute kidney injury and colitis, has occurred in adult patients treated with alpelisib in the oncology setting and may occur in patients treated with VIJOICE. In the EPIK-P1 study, 16% of patients experienced grade 1 diarrhea during treatment with VIJOICE. Monitor patients for diarrhea and additional symptoms of colitis, such as abdominal pain and mucus or blood in the stool. Interrupt, reduce the dose of, or permanently discontinue VIJOICE based on the severity of diarrhea or colitis.

Embryo-Fetal Toxicity. Based on findings in animals and its mechanism of action, VIJOICE can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VIJOICE and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use condoms and effective contraception during treatment with VIJOICE and for 1 week after the last dose.

The most common adverse reactions (all grades, incidence ≥10%) were diarrhea (16%), stomatitis (16%), and hyperglycemia (12%).

The most common laboratory abnormalities (all grades, incidence ≥20%) were decreased calcium (corrected) (60%), decreased phosphate (59%), increased glucose (56%), increased HbA1c (38%), increased creatinine (31%), increased bilirubin (29%), increased potassium (24%), decreased leukocyte (22%), decreased lymphocyte (20%), and decreased hemoglobin (20%).

The following additional adverse reactions and laboratory abnormality have been identified following administration of VIJOICE: hypersensitivity, lipase increased, dermatitis, and abdominal pain.

Please click here for full Prescribing Information.

Reference: Vijoice. Prescribing information. Novartis Pharmaceuticals Corp.

NOVARTIS

Vijoice (alpelisib) tablets 50 mg | 125 mg | 200 mg

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080