

Alpelisib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for breast cancer and phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA)-Related Overgrowth Spectrum (PROS).
- It may also be used for other reasons.
- Your care team will perform a test for specific type of abnormal PIK3CA gene to make sure alpelisib is right for you.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Alpelisib (AL-peh-LIH-sib): Piqray (PIK-ray), Vijoice (Vi-JOIZ)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	<ul style="list-style-type: none"> • Piqray: <ul style="list-style-type: none"> ○ Tablet(s) taken by mouth. • Vijoice: <ul style="list-style-type: none"> ○ Tablet(s) taken by mouth or prepared as a suspension to take or give by mouth or through a feeding tube. ○ Oral granules placed directly onto the tongue and swallowed with water, or mixed with a beverage or soft food to take or give by mouth, or mixed with water to give through a feeding tube.

Treatment Administration and Schedule

Your alpelisib dosing instructions:

- Alpelisib is available as 2 brand names: Piqray and Vijoice. Do not substitute Piqray with Vijoice. Piqray is used for breast cancer. Vijoice is used for PIK3CA-Related Overgrowth Spectrum (PROS).
- Take alpelisib 1 time each day, at about the same time each day.
- Take alpelisib with food.
- Do not change your dose or stop taking alpelisib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking alpelisib if you develop certain side effects.
- If you miss a dose of alpelisib, you may still take it with food up to 9 hours after the time you usually take it. If it has been more than 9 hours after you usually take your dose, skip the dose for that day. The next day, take the dose at your usual time. Do not take 2 doses to make up for a missed dose.

Treatment Administration and Schedule (Continued)

- If you vomit after taking a dose of alpelisib, do not take another dose on that day. Take your next dose at your usual time.
- If you take too much alpelisib, call your care team or go to the nearest hospital emergency room right away.

 Option #1: Piqray Tablets

- Alpelisib comes in 3 tablet strengths: 50 mg, 150 mg, and 200 mg. Your care team will tell you which tablets to take.
- Your dose might differ, but alpelisib is typically taken as two 150 mg tablets (300 mg total dose) by mouth once daily.
- Swallow alpelisib tablets whole. Do not chew, crush or split the tablets. Do not take any alpelisib tablets that are broken, cracked, or that look damaged.

 Option #2: Vijoice Tablets

- Alpelisib comes in 3 tablet strengths: 50 mg, 125 mg, and 200 mg. Your care team will tell you which dosage form to take.
 - If your prescribed daily dose is 50 mg, your care team may prescribe alpelisib tablets or alpelisib oral granules.
 - If your prescribed daily dose is 125 mg or 250 mg, you can only take alpelisib tablets.
- Your dose might differ, but alpelisib is typically taken as one 50 mg tablet or oral granule by mouth once daily for patients aged 2 to <18 years old, and one 200 mg and one 50 mg tablet (250 mg total dose) by mouth once daily for adult patients.
- Do not combine alpelisib tablets with alpelisib oral granules to prepare your prescribed dose.
- Alpelisib tablets can be swallowed whole, or prepared as a suspension to take or give by mouth or through a feeding tube.
- If you are taking or giving alpelisib tablets whole:
 - Swallow alpelisib tablets whole and take with food. Do not chew, divide, or crush the tablets. Do not take alpelisib tablets that are broken, cracked, or that look damaged.
- If you cannot swallow tablets whole or need to use a feeding tube, you will need to mix alpelisib tablets with water before taking or giving the dose.
- Read the detailed “Instructions for Use” that comes with alpelisib for information about the right way to prepare and take or give a dose of alpelisib.

 Option #3: Vijoice Oral Granules

- Alpelisib comes in 1 oral granule strength: 50 mg.
 - If your prescribed daily dose is 50 mg, your care team may prescribe alpelisib tablets or alpelisib oral granules.
- Your dose might differ, but alpelisib is typically taken as one 50 mg tablet or oral granule by mouth once daily for patients aged 2 to <18 years old.
- Do not use multiple packets of 50 mg oral granules or part of a packet to prepare a dose. Do not combine alpelisib tablets with alpelisib oral granules to prepare your prescribed dose.
- Alpelisib oral granules can be placed directly onto the tongue and swallowed with water, or mixed with a beverage or soft food to take or give by mouth, or mixed with water to give through a feeding tube.
- Read the detailed “Instructions for Use” that comes with alpelisib for information about the right way to prepare and take or give a dose of alpelisib tablets or oral granules.

Storage and Handling of Alpelisib

- Store alpelisib at room temperature between 68°F and 77°F (20°C and 25°C).
- People who are or may be pregnant should wear gloves when handling the medicine.
- Keep alpelisib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused alpelisib.

Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/> <hr/>
To help prevent and treat diarrhea	<hr/> <hr/> <hr/> <hr/>
To help lower the risk of rash	<hr/> <hr/> <hr/> <hr/>
To help reduce the risk of high blood sugar	<hr/> <hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<p>Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection</p>	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
<p>Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)</p>	<p>Description: RBCs and Hgb carry oxygen to your body’s tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak, very tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache
<p>Fatigue</p>	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness

<p>Mouth Sores or Irritation (Mucositis or Stomatitis)</p>	<p>Description: Treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Rinse your mouth after meals and at bedtime; rinse more often if sores develop. • Brush your teeth gently with a soft toothbrush or use a cotton swab after meals. • Use a mild, non-alcohol mouth rinse at least 4 times daily (after meals and at bedtime). Example: 1/8 teaspoon salt + 1/4 teaspoon baking soda in 8 oz warm water. • Avoid acidic, hot, spicy, rough, or crunchy foods and drinks that can irritate your mouth. • Avoid tobacco, alcohol, and alcohol-based mouthwash. • Your care team may prescribe medicines or mouth treatments to help with pain and healing. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Painful mouth sores or throat pain • Trouble eating or significant weight loss
<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods. • Your care team may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood or coffee-ground-like appearance in your vomit • Severe stomach pain that does not go away after vomiting

<p>Low Appetite</p>	<p>Description: Loss of appetite can lead to weight loss and low energy. Small changes in when and what you eat can help maintain strength and nutrition.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Be as active as you can. Do light physical activity before a meal (check with your care team before starting an exercise program). • Note times of day when your appetite is best and eat your largest meal then. • Eat 5–6 small meals or snacks each day. • Choose high-protein foods (beans, chicken, fish, meat, yogurt, tofu, eggs). Eat protein first during meals. • Choose higher-calorie foods (avoid “low-fat,” “fat-free,” or “diet” options when trying to gain/maintain weight). • If you feel full quickly, avoid drinking 30 minutes before a meal and drink liquids between meals; choose calorie-containing drinks rather than diet drinks. • Have a bedtime snack that’s easy to digest (for example, peanut butter and crackers). If you have reflux, wait at least 1 hour before lying down. • Try nutritious beverages (high-protein shakes or smoothies) if solid food is unappealing. • Ask your care team about liquid nutrition supplements and ways to add protein or calories (protein powder, yogurt, ice cream). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Unintentional weight loss • Little or no appetite for several days • Excessive tiredness or low energy
<p>Diarrhea</p>	<p>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea

<p>Kidney Problems</p>	<p>Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
<p>High Blood Sugar (Hyperglycemia)</p>	<p>Description: Treatment may cause high blood sugar levels. Your care team will do blood tests to check you for these changes and will treat you if needed.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat a well-balanced diet. • Limit sugary drinks and foods. • Eat smaller, more frequent meals. • Be physically active for at least 30 minutes most days. • Your care team may ask you to check your blood sugar at home. If you are already doing this, they may ask you to do it more frequently. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Frequent urination • Drowsiness • Increased thirst • Loss of appetite • Blurred vision • Fruity smell on your breath • Confusion • Nausea, vomiting, or stomach pain • It becomes harder to control your blood sugar
<p>High Lipase Levels in Your Blood</p>	<p>Description: Treatment may cause high levels of lipase in your blood. This may indicate a problem with your pancreas. Your care team will do blood tests to check you for these changes and will treat you if needed.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Fast heartbeat • Severe stomach-area (abdominal) pain that radiates to the back • Worsening pain after eating • Severe nausea or vomiting • Diarrhea • Yellowing of your skin or the white part of your eyes (jaundice)

<p>Rash or Itchy Skin</p>	<p>Description: Rash or itchy skin can cause redness, swelling, and a variety of bumps or patches (small red spots, welts, blisters, or scaly dry areas).</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep your skin moisturized with creams or lotions to reduce rash and itchiness. • Wear loose-fitting clothing. • Avoid perfumes and colognes, as they may worsen rash symptoms. • Limit time spent in the heat to prevent worsening symptoms. • Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn. • Wear long-sleeved clothing with ultraviolet (UV) protection and broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with sun protective factor (SPF) 30 or higher as directed. • Use lip balm with SPF 30 or higher. • Avoid tanning beds. • Your care team may recommend medicines for symptoms. 	<p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Rash or itching that continues to worsen
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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
<p>Allergic Reactions, Including Anaphylaxis and Infusion Reactions</p>	<p>Get emergency medical help right away if you develop any of the following signs or symptoms:</p> <ul style="list-style-type: none"> • Swelling of your lips, mouth, tongue, or throat • Trouble breathing or swallowing • Raised red areas on your skin (hives) • A very fast heartbeat • You feel dizzy or faint
<p>Lung Problems</p>	<ul style="list-style-type: none"> • Cough • Shortness of breath • Chest pain

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant:
 - Take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment and for 1 week after your last dose of alpelisib.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for 1 week after your last dose of alpelisib.
- **Do NOT breastfeed** during treatment and for 1 week after your last dose of alpelisib.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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