

ORAL CANCER TREATMENT EDUCATION



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ALPELISIB

Name of your medication

Generic name — alpelisib (AL-peh-LIH-sib)
Brand name — Piqray® (pik-raye)

Common uses

Alpelisib is used to treat breast cancer that has a genetic mutation called phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA). It can also be used to treat severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS).

Alpelisib may also be used for other treatments.

Dose and schedule

Taking alpelisib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of alpelisib is 300 milligrams (300 mg) to be taken by mouth at a scheduled time once a day.
- Alpelisib should be taken with food at the same time each day.
- Alpelisib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow alpelisib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of alpelisib, follow these guidelines:
 - Only take the missed dose if it has been less than 9 hours since you were supposed to take it. Then take the next dose at the regularly scheduled time.
 - Do not take the missed dose if it has been more than 9 hours since you should have taken it. Simply take the next dose at the regularly scheduled time.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose and let your care provider know about any missed doses.
- If you vomit after taking a dose, do not take an additional dose on that day. Take the next dose at the regularly scheduled time.

Drug and food interactions

- Alpelisib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Alpelisib should be taken with food.
- Grapefruit or grapefruit juice may interact with alpelisib; avoid eating or drinking this during treatment with alpelisib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

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Storage and handling

Handle alpelisib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store alpelisib at room temperature (68°F–77°F) in a dry location away from light.
- Keep alpelisib out of reach of children and pets.
- Leave alpelisib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give alpelisib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the alpelisib to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the alpelisib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder is used, a separate one should be used for alpelisib. Do not mix other medications into the box with alpelisib. The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder). When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
- If you have any unused alpelisib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of alpelisib.
- If you are traveling, put your alpelisib in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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Side Effects of Alpelisib

Below are common side effects that have been known to happen in about one-third or more of patients taking alpelisib; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High glucose levels • High lipase levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Increased hunger or thirst • Increased urination • Weakness or fatigue • Headaches • Dizziness
<p>Changes in kidney function</p>	<p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Decreased amount of urination • Unusual swelling in your legs and feet
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
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Possible Side Effect	Management
<p>Changes in liver function</p>	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
<p>Rash or itchy skin</p>	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose-fitting clothing. • Avoid using perfumes and cologne as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Prevention of rash by taking an over-the-counter medication called an antihistamine is recommended. Talk with your care provider about this before beginning alpelisib. Recommended options for non-sedating antihistamines are as follows: <ul style="list-style-type: none"> <input type="checkbox"/> Cetirizine <input type="checkbox"/> Loratadine <input type="checkbox"/> Fexofenadine <p>Sunlight can make symptoms worse.</p> <ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultraviolet) radiation occurs between the hours of 10 am and 4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. • Use lip balm with at least SPF 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

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Possible Side Effect	Management
Nausea or vomiting	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between “work” and “rest.” • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
Decreased appetite	<p>Talk to your care provider if you notice a decrease in weight while taking this medication. When you do not feel like eating, try the following:</p> <ul style="list-style-type: none"> • Small, frequent meals instead of 3 large meals each day • Keep snacks nearby so you can eat when you feel hungry. • Liquid nutritional supplements • Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.

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Possible Side Effect	Management
Mouth irritation or sores	<p>Practice good mouth care.</p> <ul style="list-style-type: none">• Rinse your mouth frequently.• Brush your teeth with a soft toothbrush or cotton swab after meals.• Use a mild non-alcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water.• If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p>

Serious side effects

- ❑ Alpelisib may cause rare but serious side effects, including the following:
 - Rarely, alpelisib can cause severe skin reactions, including Stevens-Johnson syndrome, which can be life-threatening. Seek emergency care if you have a severe rash or a rash on your mouth, eyes, or genitals.
 - Severe allergic reactions are a rare but serious side effect of alpelisib. Immediately seek medical attention if you notice difficulty breathing, swelling of the mouth or tongue, or a serious rash.
 - Alpelisib can cause swelling of your lung tissue known as non-infectious pneumonitis. Call your care team right away if you have trouble breathing, new or worsening cough, chest pain, or wheezing.
 - Alpelisib may cause inflammation in your colon. If symptoms of diarrhea or severe abdominal pain are present, please contact your health care team right away. Your health care team may have to prescribe corticosteroids in order to decrease the inflammation.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since alpelisib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take alpelisib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- ❑ Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- ❑ Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.

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- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or alpelisib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking alpelisib. Males and females of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 week after the last dose of alpelisib.
- Do not breastfeed while taking alpelisib and for 1 week after the last dose of alpelisib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

- Talk with your care provider about the process for obtaining your alpelisib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

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Additional resources

Product website: <https://www.us.piqray.com/metastatic-breast-cancer>

Product prescribing information: <https://www.novartis.us/sites/www.novartis.us/files/piqray.pdf>

Product resources: <https://www.us.piqray.com/metastatic-breast-cancer/patient-resources/financial-resources-and-access>

Updated – April 2, 2024

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, 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. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. 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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