PATIENT & CAREGIVER EDUCATION

Alpelisib

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Piqray (200 MG Daily Dose); Piqray (250 MG Daily Dose); Piqray (300 MG Daily Dose); Vijoice

Brand Names: Canada

Piqray (200 MG Daily Dose); Piqray (250 MG Daily Dose); Piqray (300 MG Daily Dose)

What is this drug used for?

Tablets (Piqray):

- It is used to treat breast cancer.

Tablets and granules (Vijoice):

- It is used to treat a health problem called PIK3CA-Related Overgrowth Spectrum (PROS).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have high blood sugar (diabetes).
- If you take any drugs (prescription or OTC, natural products, vitamins) that

must not be taken with this drug, like certain drugs that are used for HIV, infections, seizures, and others. There are many drugs that must not be taken with this drug.

- If you are breast-feeding. Do not breast-feed while you take this drug and for 1 week after your last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- High blood sugar and a diabetic blood problem (ketoacidosis) have happened. Rarely, this has been deadly. Check blood sugar as you have been told by the doctor.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If you plan to get pregnant or father a child, talk with your doctor before taking this drug.
- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- If you may become pregnant, use birth control while taking this drug and for 1 week after your last dose. If you get pregnant, call your doctor right away.
- If your sex partner may become pregnant, use a condom during sex while

taking this drug and for 1 week after your last dose. Your partner may also need to use birth control. Talk with your doctor about what types of birth control to use. If your partner gets pregnant, call the doctor right away.

- You may need to avoid donating sperm while taking this drug and for some time after. If you have questions, talk with your doctor.

Tablets (Piqray):

- This drug may be used with other drugs to treat your health condition. If you are also taking other drugs, talk with your doctor about the risks and side effects that may happen.
- If you are 65 or older, use this drug with care. You could have more side effects.

Tablets and granules (Vijoice):

- High cholesterol and triglyceride levels have happened with this drug. If you have high cholesterol or triglycerides, talk with your doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

All products:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of lung or breathing problems like shortness of breath or other trouble breathing, cough, or fever.
- Signs of kidney problems like unable to pass urine, change in how much

urine is passed, blood in the urine, or a big weight gain.

- Signs of fluid and electrolyte problems like mood changes, confusion, muscle pain or weakness, fast or abnormal heartbeat, severe dizziness or passing out, increased thirst, seizures, feeling very tired or weak, decreased appetite, unable to pass urine or change in the amount of urine produced, dry mouth, dry eyes, or severe upset stomach or throwing up.
- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Low blood cell counts have happened with this drug. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. Call your doctor right away if you have signs of infection like fever, chills, or sore throat; any unexplained bruising or bleeding; or if you feel very tired or weak.
- Severe skin reactions may happen with this drug. These include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious reactions. Sometimes, body organs may also be affected. These reactions can be deadly. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in your mouth, throat, nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.
- Diarrhea is common with this drug. Some cases of diarrhea may cause dehydration and kidney problems that can sometimes be deadly. A bowel problem (colitis) has also happened. Call your doctor right away if you have diarrhea that does not go away, severe diarrhea, mucus or blood in the stools, or severe stomach pain.

Tablets (Piqray):

- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Change in eyesight, eye pain, or severe eye irritation.

- Swelling in the arms or legs.
- Vaginal dryness.
- Flu-like signs.

Tablets and granules (Vijoice):

- Signs of skin infection like oozing, heat, swelling, redness, or pain.
- Memory problems or loss.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

Tablets (Piqray):

- Mouth sores.
- Feeling tired or weak.
- Dry skin.
- Weight loss.
- Change in taste.
- Headache.
- Stomach pain or heartburn.
- This drug may cause hair loss. Talk with a dermatologist if hair loss becomes a concern.
- Diarrhea, throwing up, upset stomach, and decreased appetite are common with this drug. If these happen, talk with your doctor about ways to lower these side effects. Call your doctor right away if any of these effects bother you, do not get better, or are severe.

Tablets and granules (Vijoice):

- Dry skin.
- Skin irritation.
- Mouth sores.
- Headache.
- Stomach pain or diarrhea.
- This drug may cause hair loss. Talk with a dermatologist if hair loss becomes a concern.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take this drug with food.
- Take this drug at the same time of day.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- If you throw up after taking a dose, do not repeat the dose. Take your next dose at your normal time.

Tablets (Piqray):

- Swallow whole. Do not chew, break, or crush.
- Do not take chipped or broken tablets.
- Another drug (metformin) may be given before this drug to help lower the risk of high blood sugar. If your doctor orders metformin for you to take before starting this drug, talk with your doctor about the benefits and risks.

Tablets (Vijoice):

- Swallow whole. Do not chew, break, or crush.
- Do not take chipped or broken tablets.
- If you are not able to swallow tablets, you can make an oral suspension using the tablets. Place tablets in 2 to 4 ounces (60 to 120 mL) of water only. Let sit for about 5 minutes. Crush the tablets with a spoon and stir well. Take right away after mixing. Throw away any part not used within 60 minutes of mixing.
- After taking your dose, rinse glass with about 1 to 2 ounces (30 to 60 mL) of water, stir with the same spoon, and drink. Repeat as needed until there are no more particles in the glass to make sure the entire dose is taken.
- Those who have feeding tubes may use this drug. Use as you have been told. Flush the feeding tube after this drug is given.

Granules (Vijoice):

- You may empty the contents of 1 packet onto your tongue. Swallow with 2 to 4 ounces (60 to 120 mL) water. If needed, rinse with more water and swallow to be sure the whole dose is taken.
- You may also pour the contents of 1 packet into a cup. Add 5 to 15 mL of water, milk, apple juice, applesauce, or yogurt. Stir and swallow right away. Rinse the cup with 2 ounces (60 mL) of water, milk, or apple juice and swallow. If any of the drug is still in the cup, repeat until the whole dose is taken.
- If you cannot take the mixture right away, it may be taken within 60 minutes

after mixing. Stir the mixture before taking it with the same spoon used to make the mixture. Throw away the mixture if it is not taken within 60 minutes after mixing.

- Those who have feeding tubes may use this drug. Use as you have been told. Flush the feeding tube after this drug is given.
- Do not use more than 1 packet for a dose. Do not use part of a packet for a dose. Do not combine packets and tablets for a dose. Do not use a packet if the seal is broken. If you have questions about how to take this drug, talk with the doctor.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it, with food.
- If it has been more than 9 hours since the missed dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any

questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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