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?

- It is used to treat a health problem called PIK3CA-Related Overgrowth Spectrum (PROS).
- If your child has been given this drug for some other reason, talk with the doctor about the benefits and risks. Talk with the doctor if you have questions or concerns about giving this drug to your child.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has high blood sugar (diabetes), talk with the doctor.
- If your child takes 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 your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug and for 1 week after the last dose.

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

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

the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's 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.
- High cholesterol and triglyceride levels have happened with this drug. If your child has high cholesterol or triglycerides, talk with the doctor.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If your child plans to get pregnant or father a child, talk with the doctor before your child takes this drug.
- If your child is of childbearing age, a pregnancy test will need to be done before starting this drug to make sure your child is not pregnant.

If your child is or may be sexually active:

- This drug may cause harm to the unborn baby if your child takes it during pregnancy.
- If your child may become pregnant, have your child use birth control while taking this drug and for 1 week after the last dose. If your child gets pregnant, call the doctor right away.
- If your child's sex partner may become pregnant, have them use a condom during sex while taking this drug and for 1 week after the last dose. Your child's partner may also need to use birth control. Talk with the doctor about what types of birth control to use. If your child's partner gets pregnant, call the doctor right away.
- Your child may need to avoid donating sperm while taking this drug and for some time after. If you have questions, talk with the doctor.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- 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 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 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 high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Signs of skin infection like oozing, heat, swelling, redness, or pain.
- Memory problems or loss.
- 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 child's doctor right away if your child has signs of infection like fever, chills, or sore throat; any unexplained bruising or bleeding; or if your child feels 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 your child has signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in the mouth, throat, nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.
- It is common to have diarrhea when taking this drug. Some cases of diarrhea may cause fluid loss and kidney problems that can sometimes be deadly. Call the doctor right away if your child has diarrhea that does not go away or if your child has severe diarrhea. Do not try to treat diarrhea without first checking with the doctor.

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 child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

All products:

- Give this drug with food.
- Give this drug at the same time of day.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.
- If your child throws up after taking this drug, do not repeat the dose.

Tablets:

- Have your child swallow whole. Do not let your child chew, break, or crush.
- Do not give your child chipped or broken tablets.
- If your child is 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. Give right away after mixing. Throw away any part not used within 60 minutes of mixing.
- After giving the dose, rinse glass with about 1 to 2 ounces (30 to 60 mL) of water, stir with the same spoon, and have your child 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:

- The contents of 1 packet may be emptied onto your child's tongue. Have your child swallow with 2 to 4 ounces (60 to 120 mL) water. If needed, rinse with more water and have your child swallow to be sure the whole dose is taken.
- The contents of 1 packet may also be poured into a cup. Add 5 to 15 mL of water, milk, apple juice, applesauce, or yogurt. Stir and have your child swallow right away. Rinse the cup with 2 ounces (60 mL) of water, milk, or apple juice and have your child swallow. If any of the drug is still in the cup, have your child repeat until the whole dose is taken. If the mixture is not swallowed within 2 hours, throw it away.
- If your child cannot take the mixture right away, it may be given within 60 minutes after mixing. Stir the mixture before giving it with the same spoon used to make the mixture. Throw away the mixture if your child does not take this drug 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 my child misses a dose?

- Give 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 child's normal.
- Do not give 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's 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

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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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