

PATIENT & CAREGIVER EDUCATION

Pralsetinib

This information from Lexicomp® 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

Gavreto

Brand Names: Canada

Gavreto

What is this drug used for?

- It is used to treat lung cancer.
- It is used to treat thyroid cancer.

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 pressure.

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- 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?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- High blood pressure has happened with this drug.

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- Have your blood pressure checked as you have been told by your doctor.
- This drug may lower the ability of the bone marrow to make blood cells that the body needs. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. If you have questions, talk with the doctor.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
 Rarely, some bleeding problems have been deadly.
- You may have more chance of getting an infection.
 Wash hands often. Stay away from people with infections, colds, or flu.
- Talk with your doctor before getting any vaccines.
 Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.
- This drug may affect how wounds heal. If you need to have surgery, you may need to stop this drug before surgery. Start taking it again after surgery as you have been told by your doctor. Call your doctor right away if you have a wound that does not heal or any other wound problems.

• This drug may affect growth in children and teens in

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some cases. They may need regular growth checks. Talk with the 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 2 weeks after your last dose. Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. If you use hormone-based birth control, use some other kind of birth control also, like condoms. If you get pregnant, call your doctor right away.
- If your sex partner may become pregnant, use birth control while taking this drug and for 1 week after your last dose. If your partner gets pregnant, call the doctor right away.

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

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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:

- 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 high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of electrolyte problems like mood changes;
 confusion; muscle pain, cramps, or spasms; weakness;

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shakiness; change in balance; an abnormal heartbeat; seizures; loss of appetite; or severe upset stomach or throwing up.

- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- 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.
- Chest pain.
- Swelling.
- A burning, numbness, or tingling feeling that is not normal.
- Redness or irritation of the palms of hands or soles of feet.
- Severe lung problems have happened with this drug. Rarely, this has been deadly. Call your doctor right away if you have signs of lung problems like shortness of breath or other trouble breathing, cough, or fever.
- Patients with cancer who take this drug may be at a greater risk of getting a severe health problem called tumor lysis syndrome (TLS). This may lead to death.

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Call your doctor right away if you have a fast or abnormal heartbeat; any passing out; trouble passing urine; muscle weakness or cramps; upset stomach, throwing up, diarrhea, or not able to eat; or feel sluggish.

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:

- Feeling dizzy, tired, or weak.
- Stomach pain.
- Dry mouth.
- Mouth irritation or mouth sores.
- Back, bone, joint, muscle, or neck pain.
- Headache.
- Change in taste.
- Constipation, diarrhea, 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.

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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.

- Take this drug on an empty stomach. Do not eat for at least 2 hours before and 1 hour after taking this drug.
- 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.

What do I do if I miss a dose?

• Take a missed dose as soon as you think about it on the same day you missed the dose.

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- If you do not think about the missed dose until the next day, skip the missed dose and go back to your normal time.
- Do not take 2 doses on the same day.

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.

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- 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

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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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