

Pralsetinib (Gavreto)

About This Medicine

PRALSETINIB (pral SE ti nib) treats lung cancer and thyroid cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Decrease in a blood protein called albumin
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Tiredness
- Fever
- Swelling of the hands, feet, or any other part of the body
- Changes in your liver function
- Electrolyte changes
- Bone and muscle pain
- Changes to your kidney function
- Cough
- High blood pressure

Note: Each of the side effects above was reported in 25% or greater of people treated with pralsetinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions



- Abnormal bleeding which can be life-threatening – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Severe high blood pressure
- Severe changes in liver function
- Inflammation (swelling) and/or scarring of the lungs, which can be life-threatening. You may have a cough and/or trouble breathing.
- Slow wound healing
- Tumor lysis syndrome: This medicine may act on the cancer cells very quickly. This may affect how your kidneys work.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

Important Information

- You may need to hold pralsetinib for 5 days prior to elective surgery and for at least 2 weeks and until adequate wound healing following major surgery. Also, if you must have emergency surgery or have an accident that results in a wound, tell the care team that you are on pralsetinib.

How to Take Your Medicine

- Swallow the medicine on an empty stomach. Do not eat for at least 2 hours before and for at least 1 hour after you take pralsetinib.
- **Missed dose:** If you miss a dose, take it as soon as you think about it on that day. If you vomit a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets. Protect from moisture.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects



- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicine that can lessen or stop your diarrhea and/or constipation.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

Food and Medicine Interactions

- This medicine should be taken on an empty stomach.
- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with pralsetinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.
- This medicine interacts with hormonal birth control (i.e., birth control pills, skin patches, vaginal rings, injections) and affects how they work. Discuss with your care team what method of birth control may be right for you during your treatment.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher



- Chills
- A headache that does not go away
- Blurry vision or other changes in eyesight
- Tiredness and/or weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Wheezing and/or trouble breathing
- Pain in your chest
- Dry cough or a cough that is bothersome
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Swelling of the hands, feet, or any other part of the body
- Weight gain of 5 pounds in one week (fluid retention)
- Decreased or very dark urine
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Pain that does not go away or is not relieved by prescribed medicines
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use a non-hormonal form of birth control while taking this medicine and for 2 weeks after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 1 week after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant. Hormonal contraceptives may not be effective with this medicine.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 week after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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