

Pralsetinib (Gavreto)

About This Drug

Pralsetinib is used to treat cancer. It is given orally (by mouth).

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 (fatigue), and raise your risk of bleeding.
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Tiredness
- Changes in your liver function
- Electrolyte changes
- Bone and muscle pain
- High blood pressure

Note: Each of the side effects above was reported in 25% or greater of patients treated with pralsetinib. Not all possible side effects are included above.

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
- Serious changes in liver function
- Scarring and/or inflammation of the lungs that causes stiffness in the lungs which makes breathing difficult and can be life-threatening.
- Slow wound healing
- Tumor lysis syndrome: This drug 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 medical 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. Talk to your doctor and/or nurse for precautions you may need to take. Also, if you must have emergency surgery, tell the doctor that you are on pralsetinib.

How to Take Your Medication

- Swallow the medicine on an empty stomach. No food should be eaten for at least 2 hours before and for at least 1 hour after pralsetinib is taken.”.
- **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, and contact your physician. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature. 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 medication 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 nurse or your doctor 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.
- 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 doctor or nurse 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 nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 doctor or nurse before you use enemas, laxatives, or suppositories.
- Ask your nurse or doctor 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 doctor or nurse if you are experiencing pain.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.

Food and Drug Interactions

- This medicine should be taken on an empty stomach.
- This drug may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist 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 drug interactions with pralsetinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking pralsetinib as this may lower the levels of the drug 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 doctor and/or nurse what method of birth control may be right for you during your treatment.

When to Call the Doctor

Call your doctor or nurse 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 weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Coughing up blood
- Wheezing or trouble breathing
- Pain in your chest
- Dry cough
- Easy bleeding or bruising
- 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
- Blood in your urine, vomit (bright red or coffee-ground) and/or stools (bright red or black/tarry)
- Pain that does not go away or is not relieved by prescribed medicines



- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, 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
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective non-hormonal methods of birth control during your cancer treatment and for 2 weeks after treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 week after your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner. **Hormonal contraceptives may not be effective with this medication.**
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should not breastfeed during treatment and for 1 week after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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