



Provincial Health Services Authority

For the Patient: Pralsetinib
Other names: GAVRETO®

- **Pralsetinib** (pral" se' ti nib) is a drug that is used to treat some types of cancer. It is a capsule that you take by mouth.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to pralsetinib before taking pralsetinib.
- **Blood tests** may be taken regularly during treatment. The dose and timing of your treatment may be changed based on the test results and/or other side effects.
- It is important to **take** pralsetinib exactly as directed by your doctor. Make sure you understand the directions.
- **Take** pralsetinib on an empty stomach.
- If you **miss a dose** of pralsetinib, take it as soon as you remember on the same day. Go back to your usual dosing time on the next day. Do NOT take more than one dose to make up for the missed dose. Be sure to mention it to your healthcare team at your next visit.
- If you **vomit** the dose of pralsetinib, do not take a second dose. Call your healthcare team during office hours for advice as a medication to prevent nausea may be required for future doses.
- Other drugs such as itraconazole (SPORANOX®) and rifampin (RIFADIN®) may **interact** with pralsetinib. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- **Avoid grapefruit and grapefruit juice** for the duration of your treatment, as these may interact with pralsetinib.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of pralsetinib.
- Pralsetinib may affect **fertility** in men and women. If you plan to have children, discuss this with your doctor before being treated with pralsetinib.
- Pralsetinib may damage sperm and harm the baby if used during pregnancy. It is best to use **birth control** while being treated with pralsetinib. Do NOT use hormonal

birth control as it may not work as well while you are taking pralsetinib. Ask your doctor how long you should continue using birth control after your treatment has ended. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment with pralsetinib and for one week after your last dose.

- **Store** pralsetinib capsules out of the reach of children, at room temperature, away from heat, light, and moisture.
- **Tell** your doctor, dentist, and other health professionals that you are being treated with pralsetinib before you receive any treatment from them.
- **Tell** your doctor if you are planning to have **surgery**. Your doctor may ask you to stop taking pralsetinib 5 days before your surgery and not restart it for at least 14 days after your surgery AND once your surgical wound has healed. This helps to lower the risk of bleeding and may prevent problems with wound healing after surgery. Always check with your doctor before stopping or restarting pralsetinib.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
<p>Nausea and vomiting may occur. If you are vomiting and it is not controlled, you can quickly become dehydrated. Most people have little or no nausea.</p>	<p>You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.* <p>Tell your healthcare team if nausea or vomiting continues or is not controlled with your antinausea drug(s).</p>
<p>Diarrhea may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated.</p>	<p>If diarrhea is a problem:</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Choices to Help Manage Diarrhea</i>.* <p>Tell your healthcare team if you have diarrhea for more than 24 hours.</p>

SIDE EFFECTS	MANAGEMENT
Constipation may sometimes occur.	<ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. Try the ideas in <i>Food Choices to Manage Constipation</i> .*
Skin rashes may sometimes occur.	If itching is very irritating, call your healthcare team. Otherwise, be sure to mention it at your next visit.
Fever may sometimes occur.	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day If you have fever (over 38°C or 100°F by an oral thermometer) plus another sign of infection, call your healthcare team immediately . Other signs of infection include chills, cough, or burning when you pass urine.
Minor bleeding, such as nosebleeds , may sometimes occur.	<ul style="list-style-type: none"> • Sit up straight and tip your head slightly forward. Tilting your head back may cause blood to run down your throat. • Pinch your nostrils shut between your thumb and forefinger or apply firm pressure against the bleeding nostril for 10 full minutes. • After 10 minutes, check to see if your nose is still bleeding. If it is, hold it for 10 more minutes. • Stay quiet for a few hours and do not blow your nose for at least 12 hours after the bleeding has stopped. • Get emergency help if a nosebleed lasts longer than 20 minutes.
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem: <ul style="list-style-type: none"> • Elevate your feet when sitting. • Avoid tight clothing.

SIDE EFFECTS	MANAGEMENT
<p>Your white blood cells may decrease during your treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.</p>	<p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. <p>Stop taking pralsetinib and call your healthcare team immediately at the first sign of an infection such as fever (over 38°C or 100°F by an oral thermometer), chills, cough, or burning when you pass urine.</p>
<p>Your platelets may decrease during your treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual.</p>	<p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • Try not to bruise, cut, or burn yourself. • Clean your nose by blowing gently. Do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. <p>Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</p> <ul style="list-style-type: none"> • Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). <p>For minor pain, try acetaminophen (e.g., TYLENOL®) to a maximum of 4 g (4000 mg) per day.</p>
<p>Sore mouth may sometimes occur a few days after treatment. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection.</p>	<ul style="list-style-type: none"> • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day. <p>Try the ideas in <i>Food Ideas to Try with a Sore Mouth</i>.*</p>

SIDE EFFECTS	MANAGEMENT
High blood pressure may sometimes occur.	Your blood pressure may be checked by your healthcare team during your visit. <ul style="list-style-type: none"> You may be asked to check your blood pressure frequently between visits. Your doctor may give you a prescription for blood pressure medication if your blood pressure is high. Tell your doctor if you are already on blood pressure medication as they may need to adjust your dose.
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle, joint, or back pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity.
Taste alteration may sometimes occur.	Try the ideas in <i>Food Ideas to Cope with Taste and Smell Changes</i> .*
Loss of appetite may sometimes occur.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*
Tiredness and lack of energy may commonly occur.	<ul style="list-style-type: none"> Do not drive a car or operate machinery if you are feeling tired. Try the ideas in <i>Fatigue/Tiredness – Patient Handout</i>.*
Hair loss does not occur with pralsetinib.	
Numbness or tingling of the fingers or toes may sometimes occur. This will slowly return to normal once your treatments are over. This may take several months.	<ul style="list-style-type: none"> Be careful when handling items that are sharp, hot, or cold. Be careful when walking on uneven surfaces or doing activities that need you to balance or be steady. Tell your healthcare team at your next visit if you have trouble with buttons, writing, picking up small objects, walking, or have fallen.

***Please ask your nurse or pharmacist for a copy.**

STOP TAKING PRALSETINIB AND CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **infection** such as fever (over 38°C or 100°F by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine;
- Signs of **bleeding problems** such as black or tarry stools, blood in urine, pinpoint red spots on skin, extensive bruising, coughing up blood, changes in speech, or confusion.
- Signs of **heart** or **lung problems** such as fast or uneven heartbeat, chest pain or chest pressure, shortness of breath or difficulty in breathing.
- Signs of **tumour lysis syndrome** such as more than one of these symptoms: abdominal pain/nausea/vomiting, dark or cloudy urine, moodiness, restlessness, confusion, shortness of breath, irregular heartbeat, unusual tiredness, fever/chills, seizure, or muscle/joint pain.

CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- New or worsening **cough**.
- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- **Trouble walking**, problems with your balance, or you have fallen.

CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Easy bruising or minor bleeding.
- Wounds or sores that are slow to heal.
- Uncontrolled high blood pressure.
- Changes in eyesight, blurry vision, or dry eyes.
- Dizziness or fainting (loss of consciousness).
- Dry mouth.
- Muscle weakness or spasms.

REPORT ADDITIONAL PROBLEMS TO YOUR HEALTHCARE TEAM
