

ORAL CHEMOTHERAPY EDUCATION



National Community Oncology
Dispensing Association, Inc.
PASSION FOR PATIENTS



PRALSETINIB

Name of your medication

Generic name — pralsetinib (pral-SEH-tih-nib)

Brand name — Gavreto® (gav-REH-toh)

Approved uses

Pralsetinib is used to treat patients with non-small cell lung cancer (NSCLC) that have a genetic characteristic called a RET gene fusion.

Dose and schedule

Taking pralsetinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of pralsetinib is 400 milligrams (400 mg) to be taken by mouth at a scheduled time each day.
- Pralsetinib should be taken on an empty stomach (at least 1 hour before or 2 hours after a meal or snack), but at the same time of day.
- Pralsetinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow pralsetinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of pralsetinib:
 - Take your pralsetinib as soon as possible on that same day. Resume the regular daily dose schedule for pralsetinib the next day.
 - Do not take 2 doses at one time.
- If you vomit after taking pralsetinib, do not take an additional dose that day. Continue with the next regularly scheduled dose of pralsetinib.

Drug and food interactions

- Pralsetinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with pralsetinib; avoid eating or drinking this during treatment with pralsetinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle pralsetinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store pralsetinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep out of reach of children and pets.
- Leave pralsetinib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give pralsetinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the pralsetinib to you, they also need to follow these steps.

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1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the pralsetinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or reminder may be used for pralsetinib. Contact your care team before using a daily pill box.
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you as the patient are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
 - If you have any unused pralsetinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of pralsetinib.
 - If you are traveling, put your pralsetinib in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Pralsetinib

Below are common side effects that have been known to happen in about one-third or more of patients taking pralsetinib; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Changes in liver function	Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following: <ul style="list-style-type: none">• Yellowing of the skin or whites of your eyes• Dark or brown urine• Bleeding or bruising

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Possible Side Effect	Management
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is OK to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Changes in kidney function</p>	<p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice either of the following:</p> <ul style="list-style-type: none"> • Decreased amount of urination • Unusual swelling in your legs and feet

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Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> High alkaline phosphatase 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> Shortness of breath Chest discomfort Weakness or fatigue New aches and pains Headaches Dizziness Swelling of your legs or feet Red- or brown-colored urine
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> Stay as active as possible, but know it is okay to rest as needed. Try to do some activity every day. Plan your activities, and do them at a time of day when you feel a bit more energetic. Avoid operating cars or machinery if you feel too tired.
<p>Constipation</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. Stay active and exercise, if possible. Eat foods high in fiber, like raw fruits and vegetables. <p>Contact your care provider if you have not had a bowel movement in 3 or more days.</p> <p>Your care provider may recommend over-the-counter medications to help with your constipation. A daily stool softener, such as docusate (Colace®), and/or a laxative, such as senna (Senokot®), may be helpful. If these do not help within 48 hours, tell your provider.</p>
<p>Muscle or joint pain or weakness</p>	<ul style="list-style-type: none"> Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. Stay as active as possible, but know that it is OK to rest as needed, too. Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider how you may ease this discomfort. Take only pain medication that has been prescribed or recommended by your care provider</p>

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Serious side effects

- Pralsetinib may be harmful to your lungs. Inform your care provider of any new difficulty breathing, cough, or fever. Your provider may stop treatment with pralsetinib if your lungs are affected.
- You may have high blood pressure while taking pralsetinib. Take your blood pressure on a regular basis, and let your care team know of any large increases in blood pressure.
- You may be at a higher risk of bleeding while taking pralsetinib. Contact your care team if you notice frequent nosebleeds, blood in your stool, bleeding that occurs by itself without injury, or bleeding that will not stop after 5 minutes of pressure.
- Pralsetinib can cause cuts or wounds to heal more slowly. Tell your care team if you have a wound that does not heal properly. Also tell your care team if you have a planned surgery or dental procedure, as pralsetinib should be stopped prior to your surgery. Your doctor may restart pralsetinib after your surgical wound has healed.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since pralsetinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take pralsetinib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or pralsetinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking pralsetinib. Men and women of childbearing age and potential should use effective nonhormonal contraception during therapy and for a minimum of 2 weeks after the last dose of these medications. Note: Pralsetinib may render hormonal contraceptives ineffective.

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- Effective contraception could include one or more of the following: barrier methods, appropriate surgical procedure (vasectomy, tubal ligation), etc.
- Do not breastfeed while taking these medications and for 1 week after the last dose.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

- Talk with your care provider about the process for obtaining pralsetinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://gavreto.com>

Product prescribing information: <https://www.blueprintmedicines.com/uspi/GAVRETO.pdf>

Product resources: <https://gavreto.com/nsclc/#patient-support>

Updated – September 19, 2020

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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