

Get to know GAVRETO™

(pralsetinib)

GAVRETO is a **once-daily targeted therapy** for people living with **RET-positive** metastatic non–small cell lung cancer (mNSCLC) or advanced thyroid cancer.

RET=rearranged during transfection.

WHAT IS GAVRETO (pralsetinib) AND HOW DOES IT WORK?

GAVRETO™ (pralsetinib) is a prescription medicine used to treat certain cancers caused by abnormal rearranged during transfection (RET) gene in:

- adults with non-small cell lung cancer (NSCLC) that has spread (metastatic)
- adults and children 12 years of age and older with advanced medullary thyroid cancer (MTC) or MTC that has spread who require a medicine by mouth or injection (systemic therapy)
- adults and children 12 years of age and older with advanced thyroid cancer or thyroid cancer that has spread who require a medicine by mouth or injection (systemic therapy) and who have received radioactive iodine and it did not work or is no longer working

Your healthcare provider will perform a test to make sure that GAVRETO is right for you.

GAVRETO was approved based on the percentage of patients whose tumor size shrank or disappeared after treatment and how long that response lasted. There are ongoing studies to confirm the benefit of GAVRETO.



Pralsetinib blocks the uncontrolled growth driven by the cancer's abnormal RET genes.



This may help slow the growth and spread of your cancer.



What is RET?



RET is a type of **gene** that everyone has within their cells. Genes are pieces of DNA that give the cells in your body instructions to perform certain functions.

In specific types of cancer cells, the **RET gene is abnormal**. Abnormal RET genes, such as **RET fusions or mutations**, drive the uncontrolled growth of cells, leading to cancer.



Abnormal RET genes may be found in both mNSCLC and advanced thyroid cancer.

RET+

If your cancer is caused by abnormal RET genes, it is referred to as **RET positive (RET+)**.

RET+=rearranged during transfection positive.

How do I take GAVRETO?

GAVRETO is not chemotherapy or immunotherapy and can be taken orally at home.

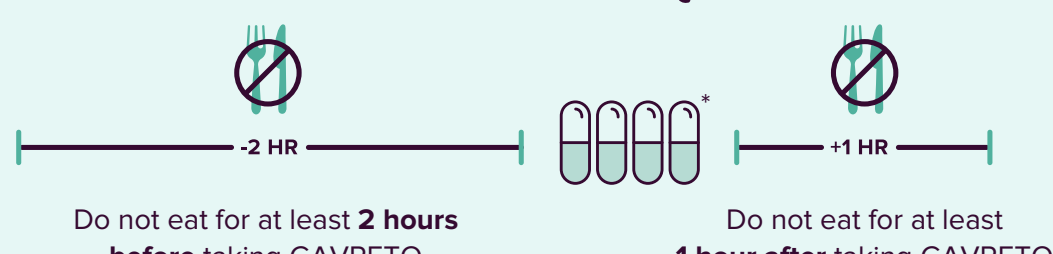
Dosing can vary from person to person. It's important to remember to take GAVRETO capsules as directed by your doctor.



Take GAVRETO once daily by mouth



Take on an empty stomach



*Assuming a recommended starting dose of 400 mg, once daily.

While taking GAVRETO: Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with GAVRETO if you develop side effects.

If you miss a dose: Take the missed dose as soon as possible on the same day. Then take your next dose of GAVRETO at your regular time the next day.

If you vomit after taking a dose: Do not take an extra dose. Take your next dose of GAVRETO at your regular time the next day.

Before taking GAVRETO, tell your healthcare provider about all of your medical conditions and all of the medicines you take. Take your prescribed dose of GAVRETO exactly as advised by your doctor. Do not change your dose or stop taking GAVRETO unless your doctor tells you to.

SERIOUS SIDE EFFECTS

GAVRETO may cause serious side effects:



Lung Problems: GAVRETO may cause severe or life-threatening inflammation of the lungs during treatment, that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including shortness of breath, cough, or fever.



High blood pressure (hypertension): High blood pressure is common with GAVRETO and may sometimes be severe. You should check your blood pressure regularly during treatment with GAVRETO. Tell your healthcare provider if you have increased blood pressure readings or get any symptoms of high blood pressure, including confusion, dizziness, headaches, chest pain or shortness of breath.



Liver problems: Liver problems (increased liver function blood test results) can happen during treatment with GAVRETO and may sometimes be serious. Your healthcare provider will do blood tests before and during treatment with GAVRETO to check you for liver problems. Tell your healthcare provider right away if you get any signs or symptoms of liver problem during treatment, including yellowing of your skin or the white part of your eyes (jaundice), loss of appetite, nausea or vomiting, dark "tea-colored" urine, pain on the upper right side of your stomach area, sleepiness, bleeding or bruising.



Bleeding problems: GAVRETO can cause bleeding which can be serious and cause death. Tell your healthcare provider if you have any signs or symptoms of bleeding during treatment, including vomiting blood or if your vomit looks like coffee-grounds, unusual vaginal bleeding, nose bleeds that happen often, pink or brown urine, drowsiness or difficulty being awakened, red or black (looks like tar) stools, confusion, coughing up blood or blood clots, headache, unusual bleeding or bruising of your skin, change in speech, or menstrual bleeding that is heavier than normal.



Tumor lysis syndrome (TLS): TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure and the need for dialysis treatment, an abnormal heartbeat, and may sometimes lead to hospitalization. Your healthcare provider may do blood tests to check you for TLS. You should stay well hydrated during treatment with GAVRETO. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with GAVRETO: nausea, shortness of breath, vomiting, muscle cramps, weakness, seizures or swelling.



Risk of wound healing problems: Wounds may not heal properly during treatment with GAVRETO. Tell your healthcare provider if you plan to have any surgery before or during treatment with GAVRETO. You should not take GAVRETO for at least 5 days before surgery. Your healthcare provider should tell you when you may start taking GAVRETO again after surgery.

COMMON SIDE EFFECTS

The most common side effects of GAVRETO include:

- › constipation
- › decreased white blood cell, red blood cell, and platelet counts
- › high blood pressure
- › decreased levels of phosphate in the blood
- › tiredness
- › decreased levels of calcium in the blood
- › muscle and joint pain
- › decreased levels of body salt (sodium) in the blood
- › diarrhea
- › abnormal liver function blood tests

GAVRETO may affect fertility in males and females, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

Your healthcare provider may temporarily stop treatment or decrease your dose, which may help your symptoms improve. If symptoms do not improve, your healthcare provider may permanently stop treatment with GAVRETO. In some patients, these problems are severe and your healthcare provider may need to have you stop taking GAVRETO.

These are not all of the possible side effects of GAVRETO. Call your doctor for medical advice about side effects.

You are encouraged to report side effects to the FDA. Visit [FDA MedWatch](https://www.fda.gov/medwatch) or call **1-800-FDA-1088**.



Have questions?

Talk to your doctor or visit [GAVRETO.com](https://www.gavreto.com) for more information and helpful resources.



YourBlueprint™ is a patient support program designed to assist you throughout your treatment with GAVRETO, including financial assistance support and more.

For more information

visit [YourBlueprint.com](https://www.YourBlueprint.com) or call **1-888-BLUPRINT (1-888-258-7768)**

Monday–Friday 8AM–8PM Eastern Time (ET)

[Click here for printer-friendly version](#)

SELECT SAFETY INFORMATION

Before taking GAVRETO, tell your healthcare provider about all of your medical conditions, including if you:

- have lung or breathing problems other than lung cancer.
- have high blood pressure
- have bleeding problems
- plan to have surgery
- are pregnant or plan to become pregnant. GAVRETO can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start GAVRETO.
- Should use an effective form of non-hormonal birth control (contraception) during treatment with GAVRETO and for 2 weeks after the final dose of GAVRETO.
- Birth control methods that contain hormones (such as birth control pills, injections or transdermal system patches) may not work as well during treatment with GAVRETO.
- Talk to your healthcare provider about birth control methods that may be right for you during this time.
- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with GAVRETO.

Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 1 week after your final dose of GAVRETO.

- are breastfeeding or plan to breastfeed. It is not known if GAVRETO passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of GAVRETO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. GAVRETO may affect the way other medicines work, and other medicines may affect how GAVRETO works.

Please see the full [Prescribing Information](#) and [Patient Information](#) for GAVRETO.



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