

YOUR GUIDE TO ONCE-DAILY

GAVRETOTM

pralsetinib | 100mg capsules



For people living with RET-positive advanced thyroid cancer.

RET=rearranged during transfection.

WHAT IS GAVRETOTM (pralsetinib)?

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

- 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.

SELECT SAFETY INFORMATION

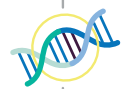
Before taking GAVRETO, tell your healthcare provider about all of your medical conditions, including if you:

- 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.

GAVRETO.COM

Please see additional Select Safety Information throughout and full [Prescribing Information](#) and [Patient Information](#).

What is RET—and why does it matter?



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.

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

RET+=rearranged during transfection positive.

What are the primary types of RET+ advanced thyroid cancer?

Abnormal RET genes may be found in several types of advanced thyroid cancers including medullary thyroid cancer (MTC), papillary thyroid cancer (PTC), follicular thyroid cancer, and Hurthle cell, but it is most commonly found in MTC and PTC.

PTC is the most common type of thyroid cancer, accounting for approximately 80% of all cases.¹ Approximately 10%-20% of PTC cases are RET+.^{2,3}

MTC is a less common type of thyroid cancer. Approximately 90% of advanced MTC cases are RET+.⁴

SELECT SAFETY INFORMATION

Before taking GAVRETO, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

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.

Please see additional Select Safety Information throughout and full [Prescribing Information](#) and [Patient Information](#).

References: **1.** American Cancer Society website. What is thyroid cancer? <https://www.cancer.org/cancer/thyroid-cancer/about/what-is-thyroid-cancer>. Accessed July 7, 2020. **2.** Drilon A, Hu ZI, Lai GGY, Tan DSW. Targeting RET-driven cancers: lessons from evolving preclinical and clinical landscapes. *Nat Rev Clin Oncol*. 2018;15(3):151-167. **3.** Kato S, Subbiah V, Marchlik E, Elkin SK, Carter JL, Kurzrock R. RET aberrations in diverse cancers: next-generation sequencing of 4,871 patients. *Clin Cancer Res*. 2017;23(8):1988-1997. **4.** Romei C, Ciampi R, Casella F, et al. RET mutation heterogeneity in primary advanced medullary thyroid cancers and their metastases. *Oncotarget*. 2018;9(11):9875-9884.

What is GAVRETO (pralsetinib) and how does it work?

Pralsetinib is a once-daily oral prescription medicine used to treat people living with **RET+ advanced thyroid cancer**.



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



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

How do I know if my cancer is RET+?

In order to determine if your cancer is RET+, your doctor may have already performed or will need to perform **biomarker testing**. The results of the test can help your doctor decide if GAVRETO is appropriate for you.

SELECT SAFETY INFORMATION

Before taking GAVRETO, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

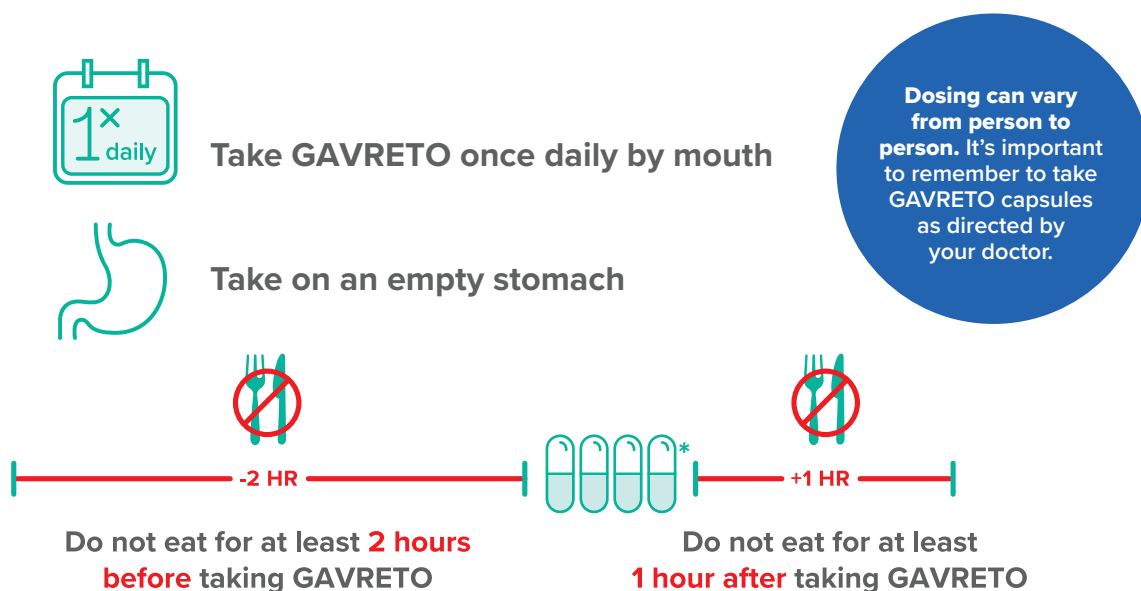
- Birth control methods that contain hormones (such as birth control pills, injections or transdermal system patches) may not work as well during treatment with GAVRETO.
- Talk to your healthcare provider about birth control methods that may be right for you during this time.
- Tell your healthcare provider 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.

Please see additional Select Safety Information throughout and full [Prescribing Information](#) and [Patient Information](#).

How do I take GAVRETO?

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.



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

If you miss a dose: Take it 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.

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

Please see additional **Select Safety Information** throughout and full [Prescribing Information](#) and [Patient Information](#).

What are the possible side effects of GAVRETO?

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.

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What are the possible side effects of GAVRETO? (cont'd)

COMMON SIDE EFFECTS

The most common side effects of GAVRETO include:

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

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.

These are not all of the possible side effects of GAVRETO.

**Call your doctor for medical advice about side effects.
You may report side effects to the FDA at 1-800-FDA-1088.**

SELECT SAFETY INFORMATION

Before taking GAVRETO, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- 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.

Please see additional Select Safety Information throughout and full [Prescribing Information](#) and [Patient Information](#).



Resources and support

Empower yourself with information and connect with support organizations and communities.

THYROID:

ThyCa: Thyroid Cancer Survivors' Association, Inc.
ThyCa.org

The Meddies Facebook Group
facebook.com/groups/MedullaryThyroidCancer

Papillary Cancer (Radioiodine-Refractory) Facebook Group
facebook.com/groups/RAIResistantThyroidCancer

Contact information for thyroid cancer support groups listed above:
thyca@thyca.org | 877-588-7904

GENERAL:

Cancer Support Community
cancersupportcommunity.org
help@cancersupportcommunity.org
Cancer Support HelpLine: 888-793-9355

CancerCare
cancercares.org
info@cancercares.org
CancerCare's Hopeline: 800-813-HOPE (4673)

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Please see additional [Select Safety Information](#) throughout and full [Prescribing Information](#) and [Patient Information](#).



YourBlueprint is a patient support program designed to assist you throughout your treatment with GAVRETO by providing:



Financial Assistance Programs*



Temporary Treatment Programs*




A Dedicated Case Manager

*For terms and conditions, call 1-888-BLUPRNT (1-888-258-7768).

WE'RE READY TO HELP YOU

Learn more about YourBlueprint™ today

 **Call 1-888-BLUPRNT (1-888-258-7768)**
Monday–Friday 8AM–8PM Eastern Time (ET) or

 **YourBlueprint.com**



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For people* living with RET+
advanced thyroid cancer.

For more information, visit GAVRETO.com/thyroid or talk to your doctor.

*The safety and effectiveness of GAVRETO have not been established in pediatric patients younger than 12 years old with RET-mutant MTC or RET-fusion thyroid cancer.



Blueprint Medicines and Genentech would like to thank
all of those who participated in our clinical trials, including
their families.

SELECT SAFETY INFORMATION

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.

The most common side effects of GAVRETO include: constipation, decreased levels of phosphate in the blood, high blood pressure, decreased levels of calcium in the blood, tiredness, decreased levels of body salt (sodium) in the blood, muscle and joint pain, diarrhea, abnormal liver function blood tests, and decreased white blood cell, red blood cell, and platelet counts.

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.

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.

Please see additional Select Safety Information throughout and full [Prescribing Information](#) and [Patient Information](#).

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12/2020 USBP-PRP-20.220.2

