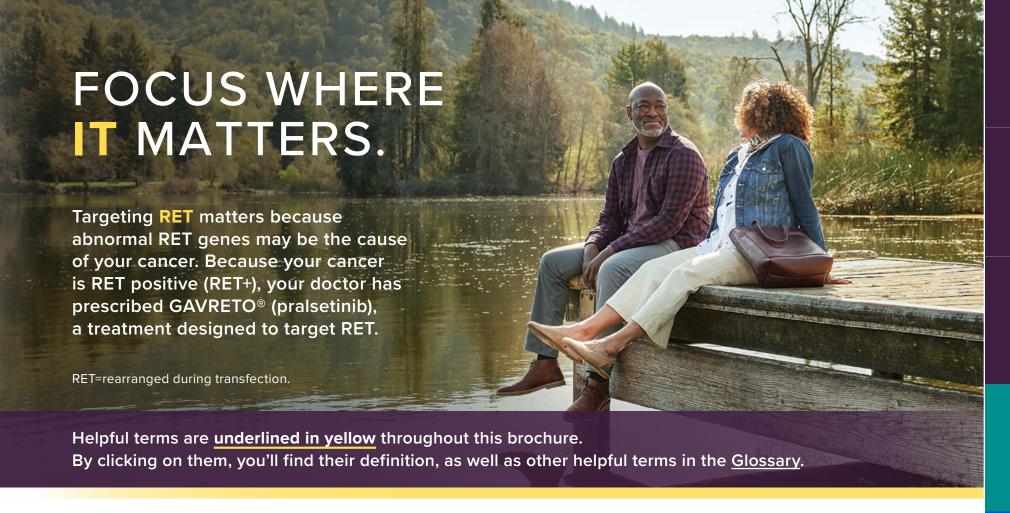


Visit **GAVRETO.com** for additional downloadable resources.



What is GAVRETO?

GAVRETO is a prescription medicine used to treat certain cancers caused by abnormal RET genes in:

- > adults with non-small cell lung cancer (NSCLC) that has spread
- 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.

It is not known if GAVRETO is safe and effective when used to treat cancers caused by abnormal RET genes in children for the treatment of NSCLC or in children younger than 12 years of age for the treatment of thyroid cancer.

*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 (see <u>page 22</u> for more details about this GAVRETO clinical study).

What is the most important information I should know about GAVRETO?

Before you get started, it's important to be aware and understand that **GAVRETO may cause serious side** effects. These serious side effects include:

- > Lung problems
- > High blood pressure (hypertension)
- > Liver problems
- Bleeding problems
- Tumor lysis syndrome (TLS)
- Risk of wound healing problems

Please see more information about serious side effects on <u>pages 11-12</u> and the most common side effects on <u>page 13</u>. Please see Important Safety Information throughout and <u>Full Prescribing Information</u>, including the <u>Patient Information</u>.



GETTING & TAKING GAVRETO

POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

This brochure was created to help you get started on GAVRETO.

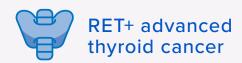
Inside you'll learn more about your specific cancer, how GAVRETO may help you, and resources and tips for living with cancer.





RET+ metastatic non-small cell lung cancer (mNSCLC)

Find specific information about **RET+ mNSCLC** in the teal tabs



Find specific information about **RET+ advanced thyroid cancer** in the **blue tabs**

HOW **GAVRETO WORKS**

It's important to know that you're not alone.

Click the buttons below for more information on support groups for your type of cancer.

FOR RET+ mNSCLC >



FOR RET+ ADVANCED THYROID CANCER

RET+=rearranged during transfection positive.

What are the most common side effects?

Before you get started, it's important to be aware and understand that GAVRETO may cause common side effects. These common side effects include:

- Muscle and joint pain
- Constipation
- Diarrhea
- Tiredness

- > Swelling of your face, arms, legs, hands, and feet (edema)
- Fever
- Cough

The most common severe abnormal blood test results with GAVRETO include:

- Decreased white blood cell, red blood cell, and platelet counts
- > Decreased levels of phosphate, body salt (sodium), calcium and potassium in the blood
- Abnormal liver function blood tests
- Increased levels of enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- Increased levels of potassium in the blood

GAVRET

Please see side effects on page 13. Please see Important Safety Information throughout and Full Prescribing Information, including the Patient Information.

GETTING & TAKING **GAVRETO**

POSSIBLE SIDE **EFFECTS**

CLINICAL STUDY **RESULTS** (mNSCLC)

CLINICAL STUDY **RESULTS** (ADV THYROID CANCER)

> **SUPPORT GROUPS** (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND **CAREGIVER SUPPORT**

GAVRETO: your quick-start guide

We understand reviewing lots of information can be overwhelming, but we strongly encourage you to review this full brochure.

These next two pages provide a summary of some important information when starting GAVRETO, which can be found throughout the brochure as well.



How do I take GAVRETO?



Do not eat for at least 2 hours before taking GAVRETO

Do not eat for at least **1 hour after** taking GAVRETO

*Assumes a recommended starting dose of 400 mg once daily. **Dosing can vary from person to person.**

- It is important to take GAVRETO exactly as your healthcare provider tells you to take it
- Take your prescribed dose of GAVRETO 1 time each day. The recommended dose is 400 mg once daily
- Take GAVRETO on an empty stomach. Do not eat for at least 2 hours before and at least 1 hour after taking GAVRETO
- > **Do not** change your dose or stop taking GAVRETO unless your healthcare provider tells you to
- 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 of GAVRETO, 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 of GAVRETO, do not take an extra dose. Take your next dose of GAVRETO at your regular time the next day

SEE ADDITIONAL TIPS FOR TAKING GAVRETO >

How do I store GAVRETO?



- At room temperature between 68°F to 77°F (20°C to 25°C)
- > Protect from moisture

Be sure to keep GAVRETO and all medicines out of the reach of children

Please see side effects on <u>pages 11-13</u>. Please see Important Safety Information throughout and Full Prescribing Information, including the Patient Information.



GETTING & TAKING GAVRETO

POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

SUPPORT & TIPS

The most common side effects of GAVRETO are:



- Muscle and joint pain
- Constipation
- Diarrhea
- > Tiredness

- Swelling of your face, arms, legs, hands, and feet (edema)
- > Fever
- > Cough

The most common severe abnormal blood test results with GAVRETO include:

- Decreased white blood cell, red blood cell, and platelet counts
- Decreased levels of phosphate, body salt (sodium), calcium and potassium in the blood
- > Abnormal liver function

- Increased levels of enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- > Increased levels of potassium in the blood

Ask your healthcare provider any questions you have about your treatment with GAVRETO.

LEARN MORE ABOUT SIDE EFFECTS >

Who can I contact for more information?





RIGEL ONECARE is here to provide guidance along your treatment journey with GAVRETO.

Visit **RigelONECARE.com** for more information.

To report side effects:

Contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch



KEEP TRACK OF NOTES AND IMPORTANT CONTACTS HERE >



GETTING & TAKING **GAVRETO**

POSSIBLE SIDE **EFFECTS**

HOW **GAVRETO WORKS**

CLINICAL STUDY **RESULTS** (mNSCLC)

CLINICAL STUDY **RESULTS** (ADV THYROID CANCER)

| SUPPORT |
|----------------|
| GROUPS |
| (mNSCLC) |

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND **CAREGIVER SUPPORT**

SUPPORT & TIPS

GAVRETO

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mNSCLC=metastatic non-small cell lung cancer; NSCLC=non-small cell lung cancer; RET+=rearranged during transfection positive.



6

KEEP TRACK OF NOTES AND IMPORTANT CONTACTS HERE >

Your specialty pharmacy is different from your regular mail-order pharmacy. It handles drugs like GAVRETO. You may not be able to get your GAVRETO right away. First, your doctor's office or specialty pharmacy will have to check to make sure your health insurance plan covers your medicine.

The specialty pharmacy may call you to find out:



How to have GAVRETO sent to your home



What type of insurance you have and how you will pay for your medicine



If you need help paying for your medicine



If you have questions about your medicine





Make sure you take and return all calls from the specialty pharmacy. Add their phone number to your contacts so that you can recognize and answer their calls promptly. If you do not respond to their calls, you may miss a refill of your prescription or receive one late.

If you're not home to receive packages, your specialty pharmacy may be able to deliver your medication to your local retail pharmacy for you to pick up at your convenience.



GAVRE

GETTING & TAKING GAVRETO

POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

SUPPORT & TIPS

Storage information

How to store GAVRETO



- > At room temperature between 68°F to 77°F (20°C to 25°C)
- Away from moisture
- > Out of the reach of children

GAVRETO can be briefly exposed to temperatures between 59°F to 86°F (15°C to 30°C) when traveling. But if you think your medicine has been exposed to extreme temperatures, please contact your pharmacy.

TIP



Contact your pharmacy or doctor if you have questions about storing or traveling with GAVRETO.



Before taking GAVRETO

What should I talk to my healthcare provider about before starting 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
- have liver problems
- > plan to have surgery
- > are pregnant or plan to become pregnant. GAVRETO can harm your unborn baby.

Women 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.

Men with women 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.

Before taking GAVRETO, tell your healthcare provider about all the medicines you take,

including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking GAVRETO with other medicines may affect how GAVRETO works.

POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

SUPPORT & TIPS

GAVRETO°

GETTING & TAKING GAVRETO

Take GAVRETO on an empty stomach (with a full glass of water) once daily by mouth. Do not eat for at least 2 hours before and at least 1 hour after taking GAVRETO.

Below is an example of how GAVRETO dosing may fit into a daily schedule:



*Assumes a recommended starting dose of 400 mg once daily. **Dosing can vary from person to person.**

- Remember to take GAVRETO capsules exactly as directed by your healthcare provider
- Do not change your dose or stop taking GAVRETO unless your healthcare provider tells you to
- Reporting side effects can help your healthcare provider decide if a lower dose may be better for you

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.

TIPS

Make GAVRETO part of your daily routine



Keep GAVRETO where you can see it



Set a daily reminder

Please see side effects on <u>pages 11-13</u>. Please see Important Safety Information throughout and <u>Full Prescribing Information</u>, including the <u>Patient Information</u>.



POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

What are the possible serious side effects?

Everyone responds to treatment differently.

GAVRETO may cause serious side effects. You may or may not experience some of the side effects described on these next two pages.



Tell your healthcare provider right away if you have any new or worsening symptoms, including those described on these next two pages. If you're experiencing side effects that require urgent attention, call 911.

GETTING & TAKING GAVRETO

POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

SUPPORT & TIPS

Lung problems



GAVRETO may cause severe or life-threatening inflammation of the lungs during treatment, that can lead to death.

Symptoms to look out for include:

- > shortness of breath
- > cough
- 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.

Symptoms to look out for include:

confusion

dizziness

headaches

> chest pain

> shortness of breath

Liver problems



Liver problems 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.

Symptoms to look out for include:

- yellowing of your skin or the white part of your eyes (jaundice)
- dark "tea-colored" urine
- > sleepiness
- bleeding or bruising

- loss of appetite
- nausea or vomiting
- pain on the upper right side of your stomach area

Bleeding problems



GAVRETO can cause bleeding which can be serious and cause death.

Symptoms to look out for include:

- vomiting blood or if your vomit looks like coffee grounds
- > pink or brown urine
- > red or black (looks like tar) stools
- > coughing up blood or blood clots
- unusual bleeding or bruising of your skin
- menstrual bleeding that is heavier than normal

- unusual vaginal bleeding
- > nose bleeds that happen often
- drowsiness or difficulty being awakened
- confusion
- headache
- > change in speech

POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

SUPPORT & TIPS

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.

Symptoms to look out for include:

-) nausea
- vomiting
- > weakness
- > swelling

- > shortness of breath
- muscle cramps
- > seizures

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

SEE THE MOST COMMON SIDE EFFECTS >

Please see Important Safety Information throughout and Full Prescribing Information, including the Patient Information.



GAVRETO

Most common side effects

The most common side effects of GAVRETO include:

- Muscle and joint pain
- Constipation
- Diarrhea
- Tiredness

- > Swelling of your face, arms, legs, hands, and feet (edema)
- > Fever
- Cough

The most common severe abnormal blood test results with GAVRETO include:

- > Decreased white blood cell, red blood cell, and platelet counts
- > Decreased levels of phosphate, body salt (sodium), calcium and potassium in the blood
- Abnormal liver function blood tests
- > Increased levels of enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- > Increased levels of potassium in the blood

TIPS THAT MAY HELP MANAGE COMMON SIDE EFFECTS >

Fertility information

GAVRETO may affect fertility in men and women, 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 healthcare provider for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

A few things to help with some common side effects

We've provided some tips that may help if you have side effects while taking GAVRETO. However, make sure to discuss any changes in your diet or daily routine with your doctor.

If you experience side effects or your symptoms worsen, call your doctor for medical advice. You may also report side effects to the FDA at 1-800-FDA-1088.





Keep track of the side effects you experience in a journal and share them with your doctor.

How should I deal with constipation?



- > Drink more liquids, like water
- > Eat more fiber (whole grains, vegetables, fruits, beans, and nuts)
- Move around more
- > Talk to your doctor about taking fiber supplements or laxatives

How can I fight tiredness and fatigue?



- Talk to your doctor about how to stay active
- Practice mind-body strategies, like meditation

- > Work with a physical therapist
- > Talk with a counselor



SIDE

EFFECTS

What can I do if I have muscle and joint pain?



- > Get a massage or work with a physical therapist
- > Talk to your doctor about medicines to treat aches, relax muscles, and reduce pain
- Apply heat or cold
- > Try some light exercise
- > Try relaxation exercises (like deep breathing and meditation)

Is there something I can do about diarrhea?



- > Avoid caffeine, alcohol, dairy, fatty foods, foods high in fiber, orange juice, prune juice, and spicy foods
- > Eat small meals and choose foods that are easy to digest (like bananas, rice, applesauce, and toast)
- Drink water and other clear liquids to prevent dehydration
- If your diarrhea is more severe or does not improve, speak with your doctor

How can I manage high blood pressure?



Follow a healthy diet:

- > Eat vegetables, fruits, white meat, and, occasionally, fish and low-fat dairy
- > Eat less red meat and salt

- > Get regular exercise (like walking, swimming, or riding a bike)
- > Talk to your doctor about medicines that help control your blood pressure

Though not a known side effect of GAVRETO, anxiety and depression are normal given the changes that are taking place in your life. It's important to know you're not alone. There are support groups available to you that may be able to help.

LEARN MORE >

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SUPPORT & TIPS

What is RET's role in mNSCLC and advanced thyroid cancers?



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

In specific types of cancer, the RET gene is abnormal.





Abnormal RET genes drive the uncontrolled growth of cells, which leads to cancer.

If your cancer is caused by abnormal RET genes, it's called "RET positive" (or "RET+").





How does **GAVRETO** (pralsetinib) work?



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



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

GAVRETO isn't chemotherapy, immunotherapy (IO), or a multikinase inhibitor (MKI). It's a targeted therapy taken by mouth, used to treat people with certain RET-altered cancers.

RET=rearranged during transfection.

What are the serious side effects of GAVRETO?

During treatment with GAVRETO, it's important to be aware and understand that GAVRETO may cause serious side effects, as seen in some patients in the clinical study. Lung problems is one of those serious side effects.

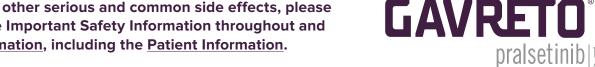
GAVRETO may cause severe or life-threatening inflammation of the lungs during treatment, that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

> shortness of breath

> cough

fever

For more information about other serious and common side effects, please see pages 11-13. Please see Important Safety Information throughout and Full Prescribing Information, including the Patient Information.





FOR RET+ ADVANCED

THYROID CANCER

FOR RET+ mNSCLC >

mNSCLC=metastatic non-small cell lung cancer; RET=rearranged during

transfection.

CLINICAL STUDY RESULTS (mNSCLC)

GETTING & TAKING

GAVRETO

POSSIBLE SIDE

EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT



Clinical study background:

GAVRETO was studied to see if it was safe and effective in adults with **RET+ mNSCLC**

What was measured in the clinical study?

1

How many adults had their tumors shrink by at least 30% (a partial response) or completely disappear (a complete response)*

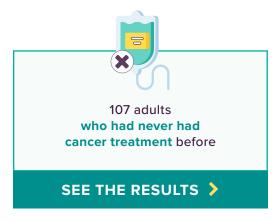


How long their response to treatment lasted

*It is important to know that a complete response (which means all tumors have responded and completely disappeared) does not mean the cancer has been cured.

Who was included in the clinical study?

237 adults with RET+ mNSCLC, including:





mNSCLC=metastatic non-small cell lung cancer; RET+=rearranged during transfection positive.

What are the serious side effects of GAVRETO?

Though GAVRETO may have benefits, it's important to be aware and understand that **GAVRETO may cause** serious side effects, as seen in some patients in the clinical study. High blood pressure (hypertension) is one of those serious side effects.

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

> shortness of breath

For more information about other serious and common side effects, please see <u>pages 11-13</u>. Please see <u>Important Safety Information throughout and Full Prescribing Information</u>, including the <u>Patient Information</u>.



GETTING & TAKING GAVRETO

POSSIBLE SIDE EFFECTS

HOW GAVRETO WORKS

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY RESULTS (ADV THYROID CANCER)

> SUPPORT GROUPS (mNSCLC)

SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND CAREGIVER SUPPORT

Clinical study background:

GAVRETO was effective in treating adults with RET+ mNSCLC

GAVRETO was approved based on the results shown on these next two pages.

GETTING & TAKING **GAVRETO**

POSSIBLE SIDE **EFFECTS**

HOW **GAVRETO WORKS**

CLINICAL STUDY RESULTS (mNSCLC)

CLINICAL STUDY **RESULTS** (ADV THYROID CANCER)

> **SUPPORT GROUPS** (mNSCLC)

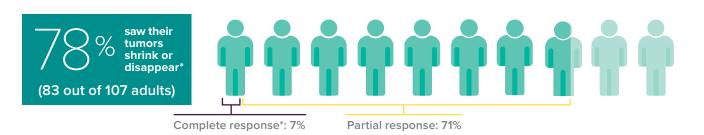
SUPPORT GROUPS (ADV THYROID CANCER)

PATIENT AND **CAREGIVER SUPPORT**

SUPPORT & TIPS



In 107 adults who had never received cancer treatment before GAVRETO:



And of those adults who had tumor shrinkage, 45% (37 out of 83 adults) saw their response to treatment last for up to 12 months or longer.

*It is important to know that a complete response (which means all tumors have responded and completely disappeared) does not mean the cancer has been cured.

mNSCLC=metastatic non-small cell lung cancer; RET+=rearranged during transfection positive.

What are the serious side effects of GAVRETO?

Though GAVRETO may have benefits, it's important to be aware and understand that GAVRETO may cause serious side effects, as seen in some patients in the clinical study. Liver problems is one of those serious side effects.

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)
- dark "tea-colored" urine
- > sleepiness

20

- loss of appetite
- nausea or vomiting

GAVRE

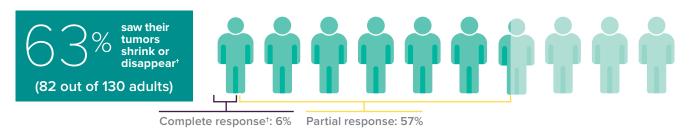
bleeding or bruising

pain on the upper right side of your stomach area

For more information about other serious and common side effects, please see pages 11-13. Please see Important Safety Information throughout and Full Prescribing Information, including the Patient Information.



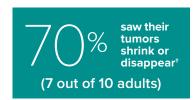
In 130 adults who had received cancer treatment before GAVRETO*:



And of those adults who had tumor shrinkage, 66% (54 out of 82 adults) saw their response to treatment last for up to 12 months or longer.



In 10 adults who had received cancer treatment before GAVRETO and had tumors that spread to the brain:



Among the 130 adults with RET+ mNSCLC who had cancer treatment in the past and received GAVRETO during the clinical study, 10 adults had tumors that spread to the brain before the study. No one received radiation therapy to the brain within 2 months before participating in the clinical study.

And of those adults who had tumor shrinkage, 71% (5 out of 7 people) saw their response to treatment last for up to 6 months or longer.

Please note that these results were only observed in a limited number of patients.

*Treatments received by patients before GAVRETO included chemotherapy, immunotherapy, multikinase inhibitors, or other systemic therapies. 'It is important to know that a complete response (which means all tumors have responded and completely disappeared) does not mean the cancer has been cured.

mNSCLC=metastatic non-small cell lung cancer; RET+=rearranged during transfection positive.

What are the serious side effects of GAVRETO?

Though GAVRETO may have benefits, it's important to be aware and understand that GAVRETO may cause serious side effects, as seen in some patients in the clinical study. Bleeding problems is one of those serious side effects.

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
- pink or brown urine
- > red or black (looks like tar) stools
- > coughing up blood or blood clots

- unusual bleeding or bruising of your skin
- menstrual bleeding that is heavier than normal
- unusual vaginal bleeding
- > nose bleeds that happen often
- being awakened
- headache

drowsiness or difficulty



change in speech

For more information about other serious and common side effects, please see pages 11-13. Please see Important Safety Information throughout and Full Prescribing Information, including the Patient Information.



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SUPPORT GROUPS (ADV THYROID CANCER)

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Clinical study background:

GAVRETO was studied to see if it was safe and effective in people with **RET+ advanced thyroid cancer**

What was measured in the clinical study?

1

How many people had their tumors shrink by at least 30% (a partial response) or completely disappear (a complete response)*

How long their

How long their response to treatment lasted

*It is important to know that a complete response (which means all tumors have responded and completely disappeared) does not mean the cancer has been cured.

Who was included in the clinical study?



9 people with papillary thyroid cancer (PTC) who had RAI therapy that did not work or was no longer working[†]

SEE THE RESULTS >

[†]People may have also been treated with sorafenib and/or lenvatinib before GAVRETO. All people had **PTC**. No people with RET+ Hürthle cell, follicular, or anaplastic thyroid cancer were intentionally left out of the clinical study because of their type of thyroid cancer. **Although GAVRETO was only studied in people with PTC**, it is still approved to be used in other types of advanced thyroid cancers that are caused by abnormal RET genes.

RAI=radioactive iodine; RET+=rearranged during transfection positive.

What are the serious side effects of GAVRETO?

Though GAVRETO may have benefits, it's important to be aware and understand that **GAVRETO may cause** serious side effects, as seen in some patients in the clinical study. Tumor lysis syndrome (TLS) is one of those serious side effects.

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

> swelling

muscle cramps

vomiting

> shortness of breath

> seizures

> weakness

For more information about other serious and common side effects, please see <u>pages 11-13</u>. Please see <u>Important Safety Information throughout and Full Prescribing Information</u>, including the <u>Patient Information</u>.



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Clinical study results:

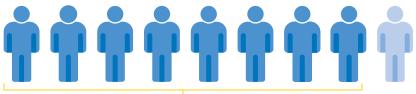
Efficacy of **GAVRETO** in people with RET+ advanced thyroid cancer

GAVRETO was approved based on the results shown below; however, the clinical study is ongoing to confirm the benefit of GAVRETO.



In 9 people with papillary thyroid cancer (PTC) who had RAI therapy that did not work or was no longer working*:





And of those people who had tumor shrinkage, 100% (8 out of 8 people) saw their response to treatment last for up to 6 months or longer.† None of these patients had their tumors completely disappear.

*People may have also been treated with sorafenib and/or lenvatinib before GAVRETO. All people had PTC.

*While the effects of treatment have lasted at least 6 months, the study is still ongoing

RAI=radioactive iodine; RET+=rearranged during transfection positive.

What are the serious side effects of GAVRETO?

Though GAVRETO may have benefits, it's important to be aware and understand that GAVRETO may cause serious side effects, as seen in some patients in the clinical study. Risk of wound healing problems is one of those serious side effects.

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

Partial response: 89%

GAVRET

GAVRETO

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For more information about other serious and common side effects, please see pages 11-13. Please see Important Safety Information throughout and Full Prescribing Information, including the Patient Information.

Patient support groups and organizations for NSCLC

You are not alone in your journey. Connect with lung cancer patient communities and organizations to stay informed and strengthen your support network.

Are you a caregiver? These organizations have resources and support specifically for you too.

RET+ CANCER SUPPORT



RETpositive

RETpositive.org

This patient driven group is dedicated to improve the quality of life and life expectancy of RET-positive cancer patients by raising awareness, providing community support and advocacy, and promoting medical research for RET-driven cancer.

info@retpositive.org

RET+ LUNG CANCER SUPPORT



THE HAPPY LUNGS PROJECT

happylungsproject.org

A group that supports researchers and clinicians in their work towards finding a cure for RET+ non-small cell lung cancer while educating and empowering patients in their own healing journey.

1-512-337-9352

LUNG CANCER SUPPORT



GO2 FOR LUNG CANCER

go2foundation.org

A national lung cancer nonprofit offering information, educational resources, and support to patients and caregivers.

1-800-298-2436 | support@go2.org



LUNGEVITY FOUNDATION

lungevity.org

The leading national lung cancer—focused nonprofit organization that provides patients and caregivers with lung cancer education, resources, and support.

1-844-360-5864 | info@LUNGevity.org

Rigel is not affiliated with these organizations, does not endorse any particular service or group, and is not responsible for the content on their websites or any services or resources they may provide. These independent advocacy groups are included as a reference for patients, and they do not imply endorsement of the company or products by the groups listed.

Descriptions of resources have been provided by advocacy groups. The information provided by these organizations is not meant to replace a doctor's medical advice. Your use of third-party websites is at your own risk and subject to the terms and conditions of use for such sites.

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Patient support groups and organizations for thyroid cancer

You are not alone in your journey. Connect with thyroid cancer patient communities and organizations to stay informed and strengthen your support network.

Are you a caregiver? These organizations have resources and support specifically for you too.

RET+ CANCER SUPPORT



RETpositive

RETpositive.org

This patient driven group is dedicated to improve the quality of life and life expectancy of RET-positive cancer patients by raising awareness, providing community support and advocacy, and promoting medical research for RET-driven cancer.

info@retpositive.org

THYROID CANCER SUPPORT



THANC FOUNDATION

The THANC Foundation supports research and education in the early detection and treatment of thyroid and head and neck cancers, advances new therapeutic approaches, and alleviates the suffering and functional impairment of patients who undergo treatment.

THANC strives to provide knowledge, hope, and support through the THANCGuide, an online resource located at

www.thancguide.org.



ThyCa THYROID CANCER SURVIVORS' ASSOCIATION, INC.

thyca.org

This international thyroid cancer nonprofit organization provides patients and their caregivers with medically reviewed thyroid cancer educational content and resources, and support as well as an annual Thyroid Cancer Survivors' Conference.

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CANCERCARE

cancercare.org

A national organization offering counseling and support groups over the phone, online, and in-person, along with educational workshops, publications, and financial and co-pay assistance.

<u>1-800-813-HOPE (4673)</u> | <u>info@cancercare.org</u>

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RIGEL ONECARE is here to provide guidance along your treatment journey with GAVRETO.



Nurse navigation



Reimbursement specialists



Financial and copay assistance

Nurses at RIGEL ONECARE are fully trained to support you and will:

Connect with your insurance plan and your healthcare providers to understand your coverage

Determine if you qualify and help you enroll in copay and financial assistance programs*

Answer any questions you may have during your treatment with GAVRETO

Be ready and available Monday-Friday 8 AM to 8 PM ET to address any questions or concerns



Call <u>1-833-RIGELOC</u> (1-833-744-3562)

Monday-Friday 8 AM to 8 PM ET to contact RIGEL ONECARE

or



Visit <u>RigelONECARE.com</u> for more infomation.



GAVRETO Copay Assistance

Eligible patients with commercial insurance pay as little as \$0 per prescription fill with GAVRETO copay assistance.* **Sign up at GAVRETOcopay.com**

*All RIGEL ONECARE programs are subject to eligibility requirements and changes. Criteria above do not represent all criteria for each program. Must be US resident or US territory resident. Restrictions apply.



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Everyday tips for living with cancer

Focus on yourself.

Taking care of yourself physically and emotionally may help lead to a more balanced life and feeling better.



Eat a balanced diet of fruits, veggies, and whole grains—and go light on the processed and fried foods.



Get moving. Whether it's yoga, walking, or swimming, exercise is good for the body and soul.

These tips are not intended to be medical advice.

Please consult with your doctor for medical advice.



Schedule some me time. Spend time with hobbies, passion projects, and family and friends.

Lean on your support network.

A cancer diagnosis can change both your life and the lives of your loved ones. Here are some things to keep in mind while you're adjusting to these changes.



Find a support network with others who are going through the same journey. **Remember: you're not alone. There are patient support groups.**



Ask a loved one to come with you or call in to your appointments to get help asking questions and keeping track of information.



Tell your loved ones and your doctor about how you're feeling or if you're having any side effects from GAVRETO.

mNSCLC=metastatic non-small cell lung cancer; RET+=rearranged during transfection positive.

Anxiety and depression are normal given the changes that are taking place in your life.
But it's important to know you're not alone.
There are support groups available to you that may be able to help.

IN RET+ mNSCLC >

IN RET+ ADVANCED THYROID CANCER

GAVRETO pralsetinib 100mg capsules

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Tips for caregivers

As a caregiver, you're an important part of the care team. There are lots of ways you can be a source of support. Here are a few ways for you to be there for your loved one:



Learn more about their disease and treatment options. Researching the disease your loved one has been diagnosed with, and the different treatments available, can help you both feel more informed.



Help take care of everyday tasks. Going to the grocery store, paying the bills, and doing laundry are all simple ways of showing you care.



Spend time together. Simple activities, like taking a walk around the block, can help you both feel a little more normal.



Schedule and attend doctor appointments. Not only can you be a shoulder to lean on, you can also help ask questions and take notes too.



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Talking to loved ones about your cancer

- > Realize how you feel first. You may feel sad, angry, or afraid, and that's okay. The first step is to know how you feel
- > Try different things until you find what works for you. By keeping other people involved and informed, it could help ease your burden. But if you or your family normally don't talk about personal issues, it's okay to not open up to everyone
- > Give details however you want. You can give as many details about your diagnosis and treatment as you'd like. But if it gets tiring, you can suggest they visit our website (GAVRETO.com) to learn more for themselves
- **Learn your trigger points and set boundaries.** Do you get upset when people talk about your disease or question your treatment decisions? Think about things people have said or could say that bother you. Then plan a reply you feel comfortable saying to change the conversation
- > Ask them how they feel. Cancer also affects everyone who cares about you. But if you're not ready to hear about their feelings, it's okay not to ask them. It can be tough enough to manage your treatment and how you feel without worrying about others





Notes to remember

| Use this space to keep track of phone numbers, things you'd like to discuss with your doctor, or other important information. | | |
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Ask your doctor questions to get the most out of your treatment.

Whether you're taking GAVRETO or caring for someone who is, here are some questions you may want to ask at your next appointment:

How will I know if GAVRETO is working?

Is the GAVRETO dose I'm starting at going to change?

What should I know about side effects? What should I do to help manage them?

What is the best way to contact you if I notice any side effects?

Is there financial support for GAVRETO?

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GLOSSARY:

Words or phrases you may hear when talking with your doctor

Abnormal RET genes: These genes drive the uncontrolled growth of cells, leading to cancer.

Advanced thyroid cancer: Thyroid cancer that has spread to nearby tissue or distant parts of the body.

Biomarker: A molecule or gene measured in tissue, blood, or other bodily fluids that can help determine the type of disease you have, how aggressive it is, and the best treatment.

Chemotherapy: Standard chemotherapy aims to stop the growth of cancer cells by blocking all rapidly dividing cells. Chemotherapy may be given by mouth, injection, or infusion, or put directly on the skin. This depends on the type and stage of cancer being treated.

Clinical study: A type of research, also known as a "clinical trial," that tests how well a medication works in people and what the side effects may be.

Complete response: All tumors have responded to a treatment and completely disappeared. This does not mean the cancer has been cured.

Comprehensive biomarker testing: Biomarker testing that is performed by your doctor that includes testing for all of the biomarkers recommended by current guidelines.

DNA: The molecules inside cells that carry genetic information and pass it from one generation to the next.

Fusion: When a gene breaks off and reattaches to another gene.

Gene: A piece of DNA that gives the cells in your body instructions to perform certain functions.

Hormone: A substance produced by glands in the body that regulates the activities of different cells and organs.

Immunotherapy (IO): A type of cancer treatment that helps your immune system fight cancer.

Metastasized/Metastatic: When cancer has spread to other parts of the body.

Multikinase inhibitor (MKI): A type of targeted therapy that targets multiple types of cancer cells.



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GLOSSARY:

Words or phrases you may hear when talking with your doctor

Non-small cell lung cancer (NSCLC): The most common type of lung cancer, named after the way cancer cells look under a microscope.

Papillary thyroid cancer (PTC): A type of cancer that forms in the thyroid and is the most common type of thyroid cancer.

Partial response: Tumors have responded to a treatment and shrunk in size by at least 30%.

Patient Information: A document for patients and caregivers that's included in the packaging of a medicine. It has information about the medicine and its use.

Prescribing Information: A document for doctors that's included in the packaging of a medicine. It has important scientific information needed for the safe and effective use of that medicine.

Radioactive iodine (RAI): A treatment that shrinks or kills thyroid cells. It is used to treat certain types of thyroid cancer.

RET: RET stands for *rearranged during transfection* and it's a type of gene that everyone has within their cells. In specific types of cancer cells, the RET gene is abnormal.

RET+ advanced thyroid cancer: A type of thyroid cancer driven by abnormal RET genes that has spread to nearby tissue or distant parts of the body.

RET+ mNSCLC: A type of lung cancer driven by abnormal RET genes that has spread to other parts of the body.

Systemic therapy: A treatment that uses drugs that travel through the bloodstream, reaching and affecting cells all over the body.

Targeted therapy: A type of cancer treatment that targets specific types of cancer cells.

Thyroid gland: A butterfly-shaped organ that makes **hormones** to help regulate your heart rate, metabolism, blood pressure, and body temperature.

Tumor lysis syndrome (TLS): When a large number of cancer cells die within a short period, releasing their contents into the blood.

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Visit **GAVRETO.com** for the latest information and resources.



