



A GUIDE FOR PATIENTS AND CAREGIVERS

Retevmo is the first FDA-approved therapy for people with *RET*-positive metastatic NSCLC

This resource contains information about treatment with Retevmo, including:

- Defining *RET*
- How Retevmo works
- What to expect while taking Retevmo
- Savings* and support options

NSCLC=non-small cell lung cancer; RET=rearranged during transfection.

*Governmental beneficiaries excluded, terms and conditions apply.

Retevmo is a prescription medicine that is 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 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 Retevmo is right for you. It is not known if Retevmo is safe and effective in children younger than 12 years of age.

Retevmo was approved based on the percentage of patients whose tumor size shrank or disappeared after treatment and how long the response lasted. Studies are ongoing to confirm the benefit of Retevmo for this use.

SELECT SAFETY INFORMATION

RETEVMO may cause serious side effects, including:

Liver problems: Liver problems (higher levels of liver enzymes) are common with RETEVMO and may sometimes be serious. Your doctor will do blood tests before and during treatment with RETEVMO to check for liver problems. Tell your doctor right away if you get any of the following symptoms of liver problems during treatment:

- 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

If you develop liver problems while taking RETEVMO, your doctor may lower your dose, stop treatment for a while, or stop treatment permanently.

Please see [Purpose and Safety Summary](#) for Retevmo on pages 10-13.



Retevmo[®]
selpercatinib capsules
40 mg • 80 mg

What is *RET*?



Metastatic NSCLC can be driven by a gene in your body.
One of those genes is *RET*

We all have something called RET in our bodies, similar to how we all have faucets in our homes. When a person has a *RET* alteration, it's like that faucet gets stuck in the "on" position, allowing water to spread, just as *RET* alterations allow cancer to grow.

Retevmo acts like a wrench that helps turn the faucet off.

Retevmo may affect both healthy cells and tumor cells, which can result in side effects, some of which can be serious.

KNOWING WHAT IS DRIVING YOUR TYPE OF
CANCER CAN HELP YOU AND YOUR DOCTOR
CHOOSE THE RIGHT TREATMENT



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Testing for *RET*

Testing for *RET* is the first step: Your doctor will perform a test to make sure Retevmo is right for you

If you are unsure about your *RET* status, talk with your doctor about biomarker testing to find out if Retevmo is the right treatment for your NSCLC.



To determine if your cancer is *RET*-positive, your doctor may opt to perform a biomarker test. A biomarker test is a type of genetic test that can tell your doctor a lot about your cancer's DNA.

Step 1: Ask

Ask your doctor if you have received a broad biomarker test for less common alterations like *RET*.

Step 2: Talk

Talk to your doctor about the results of the biomarker test.

Step 3: Treat

Treatment with Retevmo may be an option if your NSCLC tests positive for *RET*.

Certain biomarker tests require your doctor to biopsy the tumor, which means removing some tissue or blood for testing. Some biopsies are surgical, may require sedation, and come with a risk of infection. Your doctor will select the right type of biopsy for your tumor. If your tumor has been biopsied previously, some tissue may already be available for testing.

SELECT SAFETY INFORMATION

RETEVMO may cause serious side effects, including:

High blood pressure (hypertension): High blood pressure is common with RETEVMO. It may sometimes be serious. You should check your blood pressure regularly during treatment with RETEVMO. Tell your doctor if you get any of the following symptoms during treatment:

- confusion
- dizziness
- headaches
- chest pain
- shortness of breath

Please see [Purpose and Safety Summary](#) for Retevmo on pages 10-13.



Talking to your doctor



→ Gates 1-18



TRAIL
X-ING



Here are a few questions to help guide the discussion with your doctor

“Have I been tested for all biomarkers that have available treatments?”

- Ask your doctor if they recommend a broad biomarker test that can show if you have a less common alteration like *RET*. The sooner it is determined whether your NSCLC is *RET*-positive, the sooner you and your doctor can determine if Retevmo is right for you.

TO DETERMINE IF YOUR CANCER IS
RET-POSITIVE, YOUR DOCTOR MAY
OPT TO PERFORM A BIOMARKER TEST

“What does it mean to test positive for *RET*?”

- If your tumor tests positive for *RET*, this means *RET* may be what is driving your cancer.



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Retevmo can target the specific driver of *RET*-positive metastatic NSCLC

Retevmo is a targeted cancer therapy; it is not chemotherapy

Retevmo is a prescription oral therapy that was designed to block the primary driver of tumor growth in *RET*-positive metastatic NSCLC.

Retevmo may affect both healthy cells and tumor cells, which can result in side effects, some of which can be serious.

TALK TO YOUR DOCTOR TODAY TO FIND OUT
IF RETEVMO IS RIGHT FOR YOU

SELECT SAFETY INFORMATION

RETEVMO may cause serious side effects, including:

Heart rhythm changes (QT prolongation) can happen. These may be serious. RETEVMO may cause very slow, very fast, or irregular heartbeats. Tell your doctor right away if you get any of the following symptoms during treatment:

- loss of consciousness
- dizziness
- fainting
- a change in the way your heart beats (heart palpitations)

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Retevmo has been shown to shrink tumors in the majority of people with *RET*-positive metastatic NSCLC

Retevmo was studied in the largest clinical trial of people with *RET*-positive cancers. The trial included 330 people with metastatic NSCLC, and 144 had tumors that were eligible to be evaluated for shrinkage. The trial evaluated how many people responded to treatment, which means their tumors either shrank or disappeared completely, and how long the response lasted.

See how Retevmo helped people in a clinical trial with *RET*-positive metastatic NSCLC

85%

of the 39 people **who had never received any cancer treatment** had an objective response, meaning their tumors shrank by 30% or more

- Median* length of response has not yet been reached, as the trial is ongoing

64%

of the 105 people **who had prior cancer treatment**[†] had an objective response, meaning their tumors shrank by 30% or more

- Responses lasted a median* of 17.5 months

In the trial, Retevmo reduced the size of tumors in the brain in people with metastatic *RET*-positive NSCLC who had prior cancer treatments[†]

10 of the 11

people whose metastatic NSCLC had spread to their brain saw their **brain tumors shrink by at least 30% or disappear completely**

- All 10 people saw a response of 6 months or longer

*Median is the middle number in a range of numbers.

[†]Platinum-based chemotherapy; some had also received other therapies.

SELECT SAFETY INFORMATION

RETEVMO may cause serious side effects, including:

Bleeding problems: RETEVMO can cause bleeding, which can be serious and may lead to death. Tell your doctor if you have any signs of bleeding during treatment, including:

- vomiting blood or if your vomit looks like coffee-grounds
- pink or brown urine
- red or black stools that look like tar
- 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 woken up
- confusion
- headache
- change in speech



Please see [Purpose and Safety Summary](#) for Retevmo on pages 10-13.

How to take Retevmo

Retevmo is taken by itself and not in combination with additional cancer therapies

- Retevmo is taken orally twice daily, with each dose 12 hours apart
- Retevmo can be taken at home, with or without food.* Swallow the capsules whole. Do not chew or crush

Common questions about how to take Retevmo

How often should I take Retevmo?

- Take Retevmo orally twice a day, with each dose separated by 12 hours, unless your doctor tells you otherwise. Take Retevmo exactly as your doctor tells you. Your doctor may change your dose, if needed. Do not change your dose or stop taking Retevmo without talking to your doctor

If I'm taking other medicines, do these medicines affect how I take Retevmo?

*If you take:

- **a proton-pump inhibitor** (PPIs such as dexamprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole), take Retevmo with food
- **an antacid** that contains aluminum, magnesium, calcium, simethicone, or buffered medicines, take Retevmo 2 hours before or 2 hours after taking the antacid
- **an H2 blocker** (such as famotidine, nizatidine, and cimetidine), take Retevmo 2 hours before or 10 hours after taking the H2 blocker

What should I do if I miss a dose or get sick after taking a dose?

- Do not take a missed dose of Retevmo unless it is more than 6 hours until your next scheduled dose. If you get sick after taking a dose, do not take an extra dose, and take your next dose at your regular time. In the event that you take too much Retevmo, call your doctor or go to the nearest hospital emergency room right away

If you have questions about Retevmo or need more information on how to take it, you should talk to your doctor. You can also call the Lilly Oncology Support Center at **1-866-472-8663** or sign up for the [Retevmo Ongoing Support Program](#).



SELECT SAFETY INFORMATION

RETEVMO may cause serious side effects, including:

Allergic reactions: RETEVMO can cause a fever, rash, or pain in muscles or joints, especially in the first month of treatment. Tell your doctor if you get any of these symptoms. Your doctor may stop treatment for a while or lower your dose of RETEVMO.

Please see [Purpose and Safety Summary](#) for Retevmo on pages 10-13.



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What are some possible side effects?

Retevmo may cause serious side effects, including liver problems, high blood pressure (hypertension), heart rhythm changes (QT prolongation), bleeding problems, allergic reactions, risk of wound healing problems, and risk to unborn babies.

The most common side effects include:

- Increased levels of liver enzymes
- Increased blood sugar levels
- Decrease in white blood cell count
- Decreased protein levels (albumin) in the blood
- Decreased levels of calcium in the blood
- Dry mouth
- Diarrhea
- Increased creatinine (kidney function test)
- High blood pressure
- Tiredness
- Swelling of your arms, legs, hands, and feet (peripheral edema)
- Decrease in platelet count
- Increased cholesterol levels
- Rash
- Decreased levels of salt (sodium) in the blood
- Constipation

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

In a clinical trial, 5% of people stopped taking Retevmo due to side effects.

- Rare adverse reactions resulting in permanently stopping Retevmo included increased liver enzymes, serious infection, allergic reactions, fatigue, and bleeding problems

Side effects requiring dosage interruption in more than 2% of patients included increased liver enzymes, high blood pressure, diarrhea, fever, and heart rhythm changes

Side effects requiring lowered dose in more than 2% of patients included increased liver enzymes, heart rhythm changes, and fatigue

These are not all of the possible side effects of Retevmo. If you experience side effects while on treatment, it is important that you speak with your doctor or pharmacist. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call **1-800-FDA-1088**. You may also report side effects to Eli Lilly and Company at **1-800-LillyRx (1-800-545-5979)**.

You should avoid taking St. John's wort, proton-pump inhibitors (PPIs such as dextansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, rabeprazole), H2 blockers (such as famotidine, nizatidine, and cimetidine), and antacids that contain aluminum, magnesium, calcium, simethicone, or buffered medicines during treatment with Retevmo.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain other medications may affect how Retevmo works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.



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Retevmo savings* and support

Learn how you can save on Retevmo treatment and get support along the way



Retevmo Savings Card

Paying for treatment shouldn't be an additional concern for you and your loved ones, so we've created the Retevmo Savings Card, which may help you manage treatment costs.

Eligible commercially insured covered patients pay as little as \$0 a month.*

Need a Savings Card?

Visit <https://e.lilly/30xAuZS> for more information or call the Lilly Oncology Support Center at **1-866-472-8663**.



Retevmo Ongoing Support

Whether you have questions about Retevmo or just need someone to talk to, your Companion in Care™ is here for you.

Sign up to connect with a dedicated Companion in Care, who will provide personalized phone support throughout your treatment by:

- Helping to get you started on Retevmo quickly
- Focusing on the insurance process, so you can focus on treatment
- Being there to answer questions or just lend an ear
- Connecting you with resources and information

There are 3 simple ways to join:

- Enroll now at <https://e.lilly/37lftmF>
- Call the Lilly Oncology Support Center at **1-866-472-8663**
- Ask a member of your healthcare team about signing up

Retevmo Companion in Care call agents are not medical professionals. Your doctor is your source for medical advice. Companion in Care™ is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

*Offer good until 12/31/2022 or up to 12 months from patient qualification into the program, whichever comes first. Patients must have coverage for Retevmo through their commercial drug insurance coverage to pay as little as \$0 for a 30-day supply of Retevmo. Offer subject to a monthly cap and a separate annual cap. Monthly and annual caps are set at Lilly's absolute discretion and may be changed by Lilly with or without notice. Participation in the program requires a valid patient HIPAA authorization. Patient is responsible for any applicable taxes, fees, or amounts exceeding monthly or annual caps. **This offer is invalid for patients without commercial drug insurance or whose prescription claims for Retevmo are eligible to be reimbursed, in whole or in part, by any governmental program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state patient or pharmaceutical assistance program.** Offer void where prohibited by law and subject to change or discontinue without notice. Card activation is required. Subject to additional terms and conditions, which can be found at www.retevmo.com/savings-support#savings.

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Purpose and Safety Summary

Important Facts About RETEVMO® (reh-TEHV-moh). It is also known as selpercatinib.

RETEVMO is a prescription medicine that is used to treat certain cancers caused by an abnormal gene, called RET, in:

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

Your doctor will perform a test to make sure that RETEVMO is right for you.

It is not known if RETEVMO is safe and effective in children younger than 12 years of age.

WARNINGS

RETEVMO may cause serious side effects, including:

Liver problems: Liver problems (higher levels of liver enzymes) are common with RETEVMO and may sometimes be serious. Your doctor will do blood tests before and during treatment with RETEVMO to check for liver problems. Tell your doctor right away if you get any of the following symptoms of liver problems during treatment:

- 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

If you develop liver problems while taking RETEVMO, your doctor may lower your dose, stop treatment for a while, or stop treatment permanently.

High blood pressure (hypertension): High blood pressure is common with RETEVMO. It may sometimes be serious. You should check your blood pressure regularly during treatment with RETEVMO. Tell your doctor if you get any of the following symptoms during treatment:

- confusion
- headaches
- shortness of breath
- dizziness
- chest pain

Heart rhythm changes (QT prolongation) can happen. These may be serious. RETEVMO may cause very slow, very fast, or irregular heartbeats. Tell your doctor right away if you get any of the following symptoms during treatment:

- loss of consciousness
- fainting
- dizziness
- a change in the way your heart beats (heart palpitations)

Bleeding problems: RETEVMO can cause bleeding, which can be serious and may lead to death. Tell your doctor if you have any signs of bleeding during treatment, including:

- vomiting blood or if your vomit looks like coffee-grounds
- pink or brown urine
- red or black stools that look like tar
- 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 woken up
- confusion
- headache
- change in speech

CONTINUE >

Purpose and Safety Summary (continued)

WARNINGS (continued)

Allergic reactions: RETEVMO can cause a fever, rash, or pain in muscles or joints, especially in the first month of treatment. Tell your doctor if you get any of these symptoms. Your doctor may stop treatment for a while or lower your dose of RETEVMO.

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 RETEVMO. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with RETEVMO:

- nausea
- vomiting
- weakness
- swelling
- shortness of breath
- muscle cramps
- seizures

Risk of wound healing problems: Wounds may not heal well during treatment with RETEVMO. Tell your doctor if you plan to have any surgery before or during treatment with RETEVMO.

- You should stop taking RETEVMO at least 7 days before planned surgery.
- Your doctor should tell you when you may start taking RETEVMO again after surgery.

COMMON SIDE EFFECTS

The most common side effects of RETEVMO are:

- higher levels of liver enzymes
- higher blood sugar levels
- lower white blood cell count
- lower protein (albumin) levels in the blood
- lower calcium levels in the blood
- dry mouth
- diarrhea
- higher creatinine levels (this measures kidney function)
- high blood pressure
- tiredness
- swelling of your arms, legs, hands, and feet (peripheral edema)
- lower platelet count
- higher cholesterol levels
- rash
- lower salt (sodium) levels in the blood
- constipation

RETEVMO may affect the ability to have children for both females and males. Talk to your doctor if you want to have children and you are thinking about starting treatment with RETEVMO.

- RETEVMO can harm your unborn baby. You should not become pregnant during treatment with RETEVMO.
- **If you are able to become pregnant:**
 - Your doctor will do a pregnancy test before you start treatment with RETEVMO.
 - You should use effective birth control (contraception) during treatment and for at least **1 week** after the final dose of RETEVMO. Talk to your doctor about birth control methods that may be right for you.
 - Tell your doctor right away if you become pregnant or think you might be pregnant during treatment with RETEVMO.
- **Males with partners who are able to become pregnant** should use effective birth control during treatment with RETEVMO and for at least **1 week** after the final dose of RETEVMO.

These are not all the possible side effects with RETEVMO. If you are concerned about side effects, talk to your doctor. Tell your doctor about any side effects you have. You can also report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

Purpose and Safety Summary^(continued)

BEFORE USING

Before taking RETEVMO, tell your doctor about all your medical conditions, including if you:

- have liver problems
- have high blood pressure
- have heart problems, including a condition called QT prolongation
- have bleeding problems
- plan to have surgery. You should stop taking RETEVMO at least 7 days before your planned surgery.
- are pregnant or plan to become pregnant. See section above for additional information.
- are breastfeeding or plan to breastfeed. It is not known if RETEVMO passes into your breast milk. Do not breastfeed during treatment with RETEVMO and for 1 week after the last dose.

Also tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain other medicines may affect how RETEVMO works.

- You should avoid taking certain medicines when also taking RETEVMO. These include:
 - St. John's wort,
 - proton-pump inhibitors (PPIs) such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole,
 - H2 blockers such as famotidine, nizatidine, and cimetidine,
 - antacids that contain aluminum, magnesium, calcium, simethicone, or buffered medicines.

If you cannot avoid taking PPIs, H2 blockers, or antacids, see the "How to take with certain other medicines" section below for more information. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

HOW TO TAKE RETEVMO

- Take RETEVMO exactly as your doctor tells you.
- Your doctor may stop treatment or change your dose of RETEVMO if you have side effects. Do not change your dose or stop taking RETEVMO unless your doctor tells you.
- Swallow RETEVMO capsules whole. Do not chew or crush the capsules.
- RETEVMO is taken by mouth, usually 2 times a day with or without food.
- RETEVMO doses should be taken 12 hours apart.
- If you vomit after taking a dose of RETEVMO, do not take an extra dose. Take the next dose of RETEVMO at your scheduled time.
- Do not take a missed dose of RETEVMO unless it is more than 6 hours until your next scheduled dose.
- If you take too much RETEVMO, call your doctor or go to the nearest hospital emergency room right away.

HOW TO TAKE RETEVMO WITH CERTAIN OTHER MEDICINES

- If you take a PPI (such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, or rabeprazole), take RETEVMO with food.
- If you take an antacid that contains aluminum, magnesium, calcium, simethicone, or buffered medicines, take RETEVMO 2 hours before or 2 hours after taking the antacid.
- If you take an H2 blocker (such as famotidine, nizatidine, or cimetidine), take RETEVMO 2 hours before or 10 hours after taking the H2 blocker.

Purpose and Safety Summary^(continued)

LEARN MORE

For more information, call 1-800-545-5979 or go to www.Retevmo.com.

This summary provides basic information about RETEVMO. It does not include all information known about this medicine. Read the information that comes with your medicine each time your prescription is filled.

This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other health care provider about RETEVMO and how to take it. Your doctor is the best person to help you decide if RETEVMO is right for you.

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IF YOUR METASTATIC NSCLC IS *RET*-POSITIVE,
RETEVMO MAY HELP YOU REIMAGINE A NEW TOMORROW.
TALK TO YOUR DOCTOR TODAY

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

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SELECT SAFETY INFORMATION

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- | | | |
|------------|-----------------------|-----------------|
| • nausea | • swelling | • muscle cramps |
| • vomiting | • shortness of breath | • seizures |
| • weakness | | |

Please see [Purpose and Safety Summary](#) for Retevmo on pages 10-13.



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