



A GUIDE FOR PATIENTS AND CAREGIVERS

Retevmo is the first FDA-approved therapy for people with *RET*-positive advanced 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.

INDICATION

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

- adults with locally advanced non-small cell lung cancer (NSCLC) or NSCLC that has spread

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 when used in children.

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



Retevmo[®]
selpercatinib capsules
40 mg • 80 mg

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

What is *RET*?



Advanced 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:

Lung problems: RETEVMO may cause severe or life-threatening inflammation (swelling) of the lungs during treatment, that can lead to death. Tell your doctor right away if you get any new or worsening lung symptoms, including:

- shortness of breath
- cough
- fever



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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 advanced 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 advanced 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:

High blood pressure (hypertension): High blood pressure is common with RETEVMO. It may sometimes be severe. You should check your blood pressure regularly during treatment with RETEVMO. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure. Tell your doctor if you have increased blood pressure readings or get any symptoms of high blood pressure, including:

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



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

Retevmo was studied in the largest clinical trial of people with *RET*-positive cancers. The trial included 356 people with advanced NSCLC, and 316 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.

84%

of the 69 people who had never received any cancer treatment had an objective response, meaning their tumors shrank by 30% or more

- Responses lasted a median* of 20.2 months

61%

of the 247 people who had prior cancer treatment[†] had an objective response, meaning their tumors shrank by 30% or more

- Responses lasted a median* of 28.6 months

In the trial, Retevmo reduced the size of tumors in the brain in people with advanced *RET*-positive NSCLC

4 of the 5

people who had never received any cancer treatment, and whose advanced NSCLC had spread to their brain, saw their brain tumors either shrink by at least 30% or disappear completely, and 38% of responders had a response that lasted at least 12 months

14 of the 16

people who received prior cancer treatment,[†] and whose advanced NSCLC had spread to their brain, saw their brain tumors either shrink by at least 30% or disappear completely, and 39% of responders had a response that lasted at least 12 months

*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:

Heart rhythm changes (QT prolongation). RETEVMO may cause very slow, very fast, or irregular heartbeats. Your healthcare provider may perform tests before and during treatment with RETEVMO to check the activity of your heart and the levels of body salts (electrolytes) and thyroid-stimulating hormone (TSH) in your blood. Tell your doctor right away if you get any of the following symptoms:

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



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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 2 times 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**, take Retevmo with food. Examples of PPIs include dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole
- **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**, take Retevmo 2 hours before or 10 hours after taking the H2 blocker. Examples of H2 blockers include famotidine, nizatidine, and cimetidine

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**.

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 awakened
- confusion
- headache
- change in speech



What are some possible side effects?

Retevmo may cause serious side effects, including liver problems, lung problems, high blood pressure (hypertension), heart rhythm changes (QT prolongation), bleeding problems, allergic reactions, tumor lysis syndrome, risk of wound healing problems, low levels of thyroid hormone (hypothyroidism), and risk to unborn babies.

The most common side effects include:

- swelling of your arms, legs, hands, and feet (edema)
- diarrhea
- tiredness
- dry mouth
- high blood pressure
- abdominal pain
- constipation
- rash
- nausea
- headache

The most common severe abnormal laboratory test results include:

- lower white blood cell count
- higher levels of liver enzymes
- lower sodium levels in the blood
- lower calcium levels in the blood

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, 8% of people stopped taking Retevmo due to side effects.

- Adverse reactions resulting in permanently stopping Retevmo in 0.5% or more of patients included increased liver enzymes, tiredness, and serious infection (sepsis).

Side effects requiring dosage interruption in 5% or more of patients included increased liver enzymes, diarrhea, and high blood pressure (hypertension).

Side effects requiring lowered dose in 2% or more of patients included increased liver enzymes, heart rhythm changes (QT prolongation), tiredness, diarrhea, allergic reactions, and swelling of the arms, legs, hands, and feet (edema).

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 dexlansoprazole, 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. Retevmo may affect the way other medicines work, and other medicines may affect how Retevmo works, and may increase your risk of side effects. 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

- Starting a new cancer therapy can be overwhelming. Whether you have questions about your Retevmo prescription or are looking for some additional support starting treatment, The Lilly Oncology Support Center is here for you. Call **1-866-472-8663** to connect with an agent who may be able to help.

*Subject to Lilly USA, LLC's (Lilly's) right to terminate, rescind, revoke or amend the Retevmo Savings Card Program ("Card") eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, the Card expires and savings end on 12/31/2024.

Card savings are not available to patients without commercial drug insurance or who are enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program.

MONTHLY AND ANNUAL MAXIMUM SAVINGS: For patients with commercial drug insurance coverage for Retevmo: You must have commercial drug insurance that covers Retevmo and a prescription consistent with FDA-approved product labeling to pay as little as \$0 for a 1-month prescription fill of Retevmo. Month is defined as 30-days. Card savings are subject to a maximum monthly savings of wholesale acquisition cost plus usual and customary pharmacy charges and separate maximum annual savings of up to \$25,000 per calendar year. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2024.

ADDITIONAL TERMS AND CONDITIONS:

You are responsible for any applicable taxes, fees and any amount that exceeds the monthly or annual maximum benefits. Savings card activation is required. This Card may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Retevmo Savings Card Program may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at <https://www.Retevmo.com/>. Card benefits void where prohibited by law.

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Indication and Safety Summary

RETEVMO® (reh-TEHV-moh) is used to treat certain cancers caused by abnormal *RET* genes in adults with locally advanced non-small cell lung cancer (NSCLC) or NSCLC that has spread.

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 when used in children.

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

Lung problems: RETEVMO may cause severe or life-threatening inflammation (swelling) of the lungs during treatment, that can lead to death. Tell your doctor right away if you get any new or worsening lung symptoms, including:

- shortness of breath
- cough
- fever

High blood pressure (hypertension): High blood pressure is common with RETEVMO. It may sometimes be severe. You should check your blood pressure regularly during treatment with RETEVMO. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure. Tell your doctor if you have increased blood pressure readings or get any symptoms of high blood pressure, including:

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

Heart rhythm changes (QT prolongation). RETEVMO may cause very slow, very fast, or irregular heartbeats. Your healthcare provider may perform tests before and during treatment with RETEVMO to check the activity of your heart and the levels of body salts (electrolytes) and thyroid-stimulating hormone (TSH) in your blood. Tell your doctor right away if you get any of the following symptoms:

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



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CONTINUE >

Indication and Safety Summary (continued)

WARNINGS (continued)

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 awakened
- confusion
- headache
- change in speech

Allergic reactions: RETEVMO can cause a fever, rash, or pain in muscles or joints, especially during the first month of treatment. Tell your doctor if you get any of these symptoms.

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 can 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.

Low thyroid hormone levels in your blood (hypothyroidism). Your healthcare provider will do blood tests to check your thyroid function before and during treatment with RETEVMO. Tell your healthcare provider right away if you develop signs or symptoms of low thyroid hormone levels, including:

- weight gain
- feeling cold
- tiredness that worsens or does not go away
- constipation

COMMON SIDE EFFECTS

The most common side effects of RETEVMO are:

- swelling of your arms, legs, hands, and feet (edema)
- diarrhea
- tiredness
- dry mouth
- high blood pressure
- stomach-area (abdominal) pain
- constipation
- rash
- nausea
- headache

The most common severe abnormal laboratory test results with RETEVMO include decreased white blood cell count, increased liver enzymes, decreased levels of sodium in the blood, and decreased levels of calcium in the blood.

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.



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CONTINUE >

Indication and Safety Summary (continued)

COMMON SIDE EFFECTS (continued)

- **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 **1 week** after your last 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 **1 week** after your last 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.

BEFORE USING

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

- have liver problems
- have lung or breathing problems other than lung cancer
- 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 your last dose.

Also tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RETEVMO may affect the way other medicines work and other medicines may affect how RETEVMO works, and may increase your risk of side effects.

- 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 change your dose, temporarily stop, or permanently stop treatment with 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 crush or chew the capsules.
- RETEVMO is taken by mouth, usually 2 times a day, about 12 hours apart.
- Take RETEVMO with or without food.
- 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.



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CONTINUE >

Indication and Safety Summary (continued)

HOW TO TAKE RETEVMO (continued)

- 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.

LEARN MORE

RETEVMO is a prescription medicine. 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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