

About Retevmo®

(selpercatinib, 40mg & 80mg capsules)

In a time when exciting new targeted cancer treatments are being made available to patients, Retevmo® is the first therapy specifically approved for people with certain *RET*-driven metastatic non-small cell lung cancer (NSCLC) and advanced or metastatic thyroid cancers.¹



What is Retevmo?

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, and
- 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 and who have received radioactive iodine and it did not work or is no longer working.



LUNGS



THYROID

A doctor will perform a test to make sure that Retevmo is right for a patient.

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.

RET = rearranged during transfection.

How does Retevmo work?

Retevmo is a targeted therapy, which means it was designed to target the specific driver of certain *RET*-driven advanced or metastatic cancers.^{1,2}

RET is a gene that everyone has. But, for some people, changes in *RET* can drive cells to multiply abnormally, creating a potentially cancerous tumor.^{2,3}

We all have something called *RET* in our bodies, similar to how we 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.^{1,2,4}

Retevmo may affect both healthy cells and tumor cells, which can result in side effects, some of which can be serious.¹



How was Retevmo evaluated?

Retevmo was studied in a clinical trial of 702 people with *RET*-driven metastatic non-small cell lung cancer (NSCLC), and advanced or metastatic medullary thyroid cancer (MTC) and other thyroid cancers, including papillary, poorly differentiated, anaplastic, and Hurthle cell.¹



The trial evaluated how many people responded to treatment, which means their tumors either shrank or disappeared completely, and how long the response lasted. People enrolled in the trial took Retevmo twice daily until their disease got worse or they were no longer able to tolerate treatment.¹

How is Retevmo taken?

Retevmo is taken orally twice daily, with each dose 12 hours apart.¹

Retevmo can be taken at home, with or without food.* Retevmo capsules should be swallowed whole. Retevmo capsules should not be chewed or crushed.¹



SELECT IMPORTANT SAFETY INFORMATION

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.

Learn more about what Retevmo can do for people living with *RET*-driven metastatic lung cancer and advanced or metastatic thyroid cancers¹ at www.retevmo.com.

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.¹

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

*If you take¹:

- a proton-pump inhibitor (PPIs such as dexlansoprazole, 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.¹

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.

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

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 heart beat, 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.

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.

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.

SE CON BS 25MAR2021

1. Retevmo (selpercatinib) [package insert]. Indianapolis, IN: Eli Lilly and Company; 2020.
2. Drlon A, Hu ZL, Lai GGY, et al. Targeting RET-driven cancers: lessons from evolving preclinical and clinical landscapes. *Nat Rev Clin Oncol*. 2018;15(3):151-167.
3. RET gene. National Cancer Institute. <https://ghr.nlm.nih.gov/gene/RET>. Published January 21, 2020. Accessed February 7, 2020.
4. Pinheiro APM, Pocock RH, Dixon MD, et al. Using metaphors to explain molecular testing to cancer patients. *Oncologist*. 2017;22:445-449.

Retevmo® is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

PP-SE-US-0664 04/2021 ©Lilly USA, LLC 2021. All rights reserved.