

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 (systemic therapy), 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 (systemic therapy) 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.

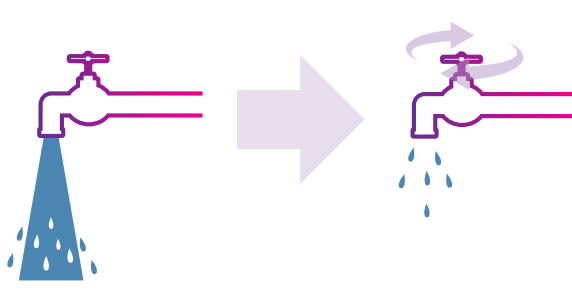
How does Retevmo work?

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 (increased 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 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 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 (increased 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

Your doctor may temporarily stop treatment, lower your dose, or permanently stop RETEVMO if you develop liver problems with RETEVMO.

High blood pressure (hypertension): High blood pressure is common with RETEVMO and 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:

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

Heart rhythm changes (QT prolongation): can occur and 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:

- 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 with RETEVMO, 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
- drowsiness or difficulty being awakened
- confusion
- headache
- change in speech

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

Risk of wound healing problems: Wounds may not heal properly 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 include:

- increased levels of liver enzymes
- increased blood sugar levels
- decreased levels of calcium in the blood
- dry mouth
- diarrhea
- increased creatinine (kidney function test)
- high blood pressure
- tiredness
- decrease in white blood cell count
- decreased protein levels (albumin) in the blood
- 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 doctor if this is a concern for you. These are not all the possible side effects with RETEVMO.

Tell your doctor if you have any side effects. **You can 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. 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.
 - Females who are able to become pregnant** 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 female 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.
- 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.
- 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 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), and antacids that contain aluminum, magnesium, calcium, simethicone, or buffered medicines during treatment with RETEVMO. If you cannot avoid taking PPIs, H2 blockers, or antacids, see the "How to take" 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

- 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.
- RETEVMO is taken by mouth, usually 2 times a day with or without food.
- If you take a proton-pump inhibitor (PPI; such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole), take RETEVMO with food.
- RETEVMO doses should be separated by 12 hours.
- 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, and cimetidine), take RETEVMO 2 hours before or 10 hours after taking the H2 blocker.
- Swallow RETEVMO capsules whole. Do not chew or crush the capsules.
- 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.

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 description is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other doctor 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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1. Retevmo (selpercatinib) [package insert]. Indianapolis, IN: Eli Lilly and Company; 2020.

2. Drlion A, Hu ZI, 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.

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