PATIENT INFORMATION
RETEVMO™ (reh-TEHV-moh)
(selpercatinib) capsules

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).
- 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.

Before taking RETEVMO, tell your healthcare provider 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. See "What are the possible side effects of RETEVMO?".
- 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 healthcare provider 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 healthcare provider about birth control methods that may be right for you.
  - Tell your healthcare provider 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 healthcare provider 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 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. If you cannot avoid taking PPIs, H2 blockers, or antacids, see “How should I take RETEVMO?” for more information on how to take RETEVMO with these medicines. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take RETEVMO?
- Take RETEVMO exactly as your healthcare provider tells you.
- Your healthcare provider 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 healthcare provider tells you.
- RETEVMO is taken by mouth, usually 2 times a day with or without food.
- If you take a proton-pump inhibitor (PPIs such as dextansoprazole, 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 healthcare provider or go to the nearest hospital emergency room right away.

**What are the possible side effects of RETEVMO?**

**RETEVMO may cause serious side effects, including:**

- **Liver problems.** Liver problems (increased liver enzymes) are common with RETEVMO and may sometimes be serious. Your healthcare provider will do blood tests before and during treatment with RETEVMO to check for liver problems. Tell your healthcare provider 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
  Your healthcare provider 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 healthcare provider if you get any of the following symptoms:
  - confusion
  - headaches
  - shortness of breath

- **Heart rhythm changes (QT prolongation)** can occur and may be serious. RETEVMO may cause very slow, very fast or irregular heartbeats. Tell your healthcare provider right away if you get any of the following symptoms:
  - loss of consciousness
  - fainting

- **Bleeding problems.** RETEVMO can cause bleeding which can be serious and may lead to death. Tell your healthcare provider 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

- **Allergic reactions.** RETEVMO can cause a fever, rash, muscle or joint pain, especially in the first month of treatment. Tell your healthcare provider if you get any of these symptoms. Your healthcare provider may temporarily stop treatment or lower your dose of RETEVMO.
- **Tumor lysis syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. TLS can cause kidney failure, the need for dialysis treatment, and an abnormal heartbeat. TLS 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 properly during treatment with RETEVMO. Tell your healthcare provider 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 healthcare provider should tell you when you may start taking RETEVMO again after surgery.

The most common side effects of RETEVMO 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.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store RETEVMO?**
- Store RETEVMO capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep RETEVMO and all medicines out of the reach of children.

**General information about the safe and effective use of RETEVMO.**
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use RETEVMO for a condition for which it was not prescribed. Do not give RETEVMO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for more information about RETEVMO that is written for health professionals.

**What are the ingredients in RETEVMO?**
**Active ingredient:** selpercatinib
**Inactive ingredients:** microcrystalline cellulose, colloidal silicon dioxide
Capsule: gelatin, titanium dioxide and edible ink
**Marketed by:** Lilly USA, LLC, Indianapolis, IN 46285, USA
RET-0002-PPI-20210128
For more information, go to www.RETEVMO.com or call 1-800-545-5979

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 01/2021