PATIENT INFORMATION

RETEVMO® (reh-TEHV-moh)
(selpercatinib)
capsules

RETEVMO® (reh-TEHV-moh)
(selpercatinib)
tablets

What is RETEVMO?

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.
- adults and children 2 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 2 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.
- adults and children 2 years of age and older with locally advanced solid tumors (cancers) or solid tumors that have spread, and have gotten worse (progressed) on or after other treatment or there are no satisfactory treatment options.

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 younger than 2 years of age for the treatment of:
  - advanced MTC or MTC that has spread who require a medicine by mouth or injection.
  - advanced thyroid cancer or thyroid cancer that has spread who require a medicine by mouth or injection, and have received radioactive iodine and it did not work or is no longer working.
  - locally advanced solid tumors or solid tumors that have spread, and have gotten worse on or after other treatment or there are no satisfactory treatment options.
- in children for other conditions.

Before taking RETEVMO, tell your healthcare provider 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. 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 **1 week** after your last 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 **1 week** after your last 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 your last dose.

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.

During treatment with RETEVMO, 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
- antacids that contain aluminum, magnesium, calcium, simethicone, or buffered medicines

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 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 healthcare provider tells you.
- Swallow RETEVMO capsules and tablets whole. Do not crush or chew.
- Do not give RETEVMO capsule to your child if they are unable to swallow a capsule.
- Take RETEVMO with or without food.
- If you take a proton-pump inhibitor (PPIs), such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole, take RETEVMO with food.
- 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.
- 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 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.

What are the possible side effects of RETEVMO?

RETEVMO may cause serious side effects, including:

- **Liver problems.** Liver problems (increased liver enzymes) can happen during treatment 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
  - 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 of the lungs during treatment, that can lead to death. Tell your healthcare provider right away if you have any new or worsening lung symptoms, including:
  - shortness of breath
  - cough
  - fever
- **High blood pressure (hypertension).** High blood pressure is common with RETEVMO and 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 healthcare provider 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 healthcare provider 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 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
  - 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 during the first month of treatment. Tell your healthcare provider if you get any of these symptoms.
- **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.
- **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 that does not go away
  - constipation
- **Hip joint problems (slipped capital femoral epiphysis or slipped upper femoral epiphysis) in children.** Tell your healthcare provider right away if you develop signs and symptoms of hip problems, including hip or knee pain or a painless limp.

The most common side effects of RETEVMO in adults with solid tumors include:

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

The most common side effects of RETEVMO in children 2 years and older with solid tumors include:

- muscle and bone pain
- diarrhea
- headache
- nausea
- vomiting
- coronavirus infection
- stomach-area (abdominal) pain
- tiredness
- fever
- bleeding

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

The most common severe abnormal laboratory test results with RETEVMO in children 2 years and older with solid tumors include decreased levels of calcium in the blood, decreased red blood cell count, and decreased white blood cell count.

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.

These are not all the possible side effects with RETEVMO.
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 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
Capsules: colloidal silicon dioxide and microcrystalline cellulose. The 40 mg capsule shell contains: gelatin, titanium dioxide, ferric oxide black and black ink. The 80 mg capsule shell contains: gelatin, titanium dioxide, FD&C blue #1 and black ink. The black ink contains: shellac, potassium hydroxide and ferric oxide black.

Tablets: croscarmellose sodium, hydroxypropyl cellulose, mannitol, microcrystalline cellulose, and sodium stearyl fumarate. The tablet film coating material contains polyvinyl alcohol, titanium dioxide, polyethylene glycol, and talc.

Additionally, the film coating of the 40 mg, 80 mg, and 120 mg tablets contains ferrosoferric oxide and the film coating of the 80 mg, 120 mg, and 160 mg tablets contain ferric oxide.

Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA

RET-0006-PPI-20240612

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 06/2024