

Retevmo[®]: now in tablet form with four dose strengths

Retevmo is switching from capsules to tablets, including more dose strengths. Retevmo capsules are offered in 40 mg and 80 mg strengths; Retevmo tablets are offered in 40 mg, 80 mg, 120 mg, and 160 mg strengths.

What's changing?

Capsule	Tablet
Gelatin-coated capsule	Film-coated tablet
Two dose strengths	Smaller than Retevmo capsules
	Four dose strengths
	Potential to require fewer tablets per day at higher doses*

*While Retevmo dosing recommendation remains twice daily, patients may be able to take a lower pill count at each dose interval.

Tablet and capsule renderings shown may vary in size and color compared to actual tablets and capsules. Color, size, and texture may differ slightly due to differences in digital screen settings and/or printer capabilities.

Please note that for a period of time, patients may receive either the original capsule formulation or the reformulated Retevmo tablets, based on Specialty Pharmacy inventory.

How to take Retevmo

How often should I take Retevmo?

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 H2 blocker, take Retevmo 2 hours before or 10 hours after taking the H2 blocker. Examples of H2 blockers include famotidine, nizatidine, and cimetidine
 - an antacid that contains aluminum, magnesium, calcium, simethicone, or buffered medicines, take Retevmo 2 hours before or 2 hours after taking the antacid

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 Lilly Support Services at 1-800-LillyRx

INDICATIONS 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.
- 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.

* This use is approved based on how many patients responded to treatment and how long they responded. Studies are ongoing to provide additional information about clinical benefit of Retevmo for this use.

Warnings

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 doctor will do blood tests before and during treatment with RETEVMO to check for liver problems. Tell your doctor right



Retevmo®
selpercatinib tablets
40 mg • 80 mg • 120 mg • 160 mg

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)

INDICATIONS AND SAFETY SUMMARY (cont'd)

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. 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 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

Hip joint problems (slipped capital femoral epiphysis or slipped upper femoral epiphysis) in children. Tell your healthcare provider right away if you develop sign and symptoms of hip problems, including hip or knee pain or a painless limp.

Common side effects

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.

INDICATIONS AND SAFETY SUMMARY (cont'd)

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 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 healthcare provider 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 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 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.



Retevmo[®]
selpercatinib tablets
40 mg • 80 mg • 120 mg • 160 mg

- 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 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 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 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 break, crush, or chew.
- Do not give RETEVMO capsules to your child if they are unable to swallow a capsule.
- 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.

INDICATIONS AND SAFETY SUMMARY (cont'd)

- 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.

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 H2 blocker (such as famotidine, nizatidine, or 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.

Learn more

RETEVMO is a prescription medicine available as 40 mg and 80 mg capsules, and 40 mg, 80 mg, 120 mg, and 160 mg tablets. 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 ALL 12JUN2024



Retevmo[®]
selpercatinib tablets
40 mg • 80 mg • 120 mg • 160 mg