

Selpercatinib (Retevmo™)

Pronounced: SEL-per-KA-tih-nib

Classification: Kinase inhibitor; RET kinase inhibitor

About Selpercatinib (Retevmo[™])

Selpercatinib is a kinase inhibitor. A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells.

Selpercatinib is a type of targeted therapy that blocks a protein called "rearranged during transfection" (RET). Abnormal genes can cause the RET protein to fuse with another protein. The "RET fusion" leads to uncontrolled cell growth and cancer. By inhibiting RET, this medication can slow or stop tumor growth. Your oncology team will test your tumor for this abnormality, which must be present in order to receive the medication.

How to Take Selpercatinib (Retevmo[™])

Selpercatinib is taken as a capsule by mouth, with or without food, twice daily (approximately 12 hours apart). Swallow the capsule whole. Do not crush, chew or open the capsules. Do not take a missed dose unless it is more than 6 hours until next scheduled dose. If you vomit after taking your dose do not take an extra dose. Instead, take your next dose as scheduled.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include (but are not limited to): St. John's wort, grapefruit, grapefruit juice, itraconazole, diltiazem, fluconazole, verapamil, rifampin, bosentan, efavirenz, repaglinide, and midazolam.

Tell your provider if you take medication for "heartburn" as these may affect how your cancer medication works. You should not take selpercatinib at the same time as some heartburn medications and others may require selpercatinib to be taken with food. Some examples of heartburn medications include proton pump inhibitors (PPIs), such as omeprazole (Prilosec®), lansoprazole (Prevacid®), pantoprazole (Protonix®); H2 blockers, such as famotidine (Pepcid®); and antacids, such as calcium carbonate (Tums®) and calcium carbonate with magnesium hydroxide (Rolaids®). If needed, please ask your care team the best heartburn medication to use and when to take it. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pouring the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Selpercatinib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Selpercatinib

There are a number of things you can do to manage the side effects of selpercatinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Liver Toxicity

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

High Blood Sugar

This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

Electrolyte Abnormalities

This medication can affect the normal levels of electrolytes (calcium, sodium, magnesium, potassium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

Xerostomia (Dry Mouth)

This medication can cause xerostomia, also known as dry mouth. Xerostomia can be uncomfortable and can affect your speech, swallowing and dental health. Ways to manage this side effect include:

- Perform frequent oral hygiene with toothpaste containing fluoride.
- Floss once a day, if your care team says you can.
- Chew sugar-free gum or suck on sugar-free candy to stimulate saliva production.
- Rinse your mouth frequently to keep the mouth moist.
- Speak to your providers about over the counter and prescription gels and rinses that act as saliva replacement.

Speak to your provider if this side effect continues to be a problem.

Kidney Problems

This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

Diarrhea

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

High Blood Pressure (Hypertension)

This medication can cause high blood pressure (hypertension). Be sure to tell your provider of any history of high blood pressure before starting selpercatinib. Patients should have their blood pressure checked before starting selpercatinib and regularly during therapy. Any hypertension should be treated appropriately. If hypertension cannot be controlled, the medication may be stopped. Report any headaches, vision changes or dizziness to your oncology care team.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Swelling (Edema)

This medication can cause swelling in the face, especially around the eyes, and extremities (hands, arms, legs, ankles, and feet). The swelling can become uncomfortable. This can also be a sign of other problems, so be sure to notify your oncology care team if you are experiencing any new or worsening swelling.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums, or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as ibuprofen (Motrin®/Advil®), naproxen (Aleve®), celecoxib (Celebrex®), etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

High Cholesterol

This medication can cause high cholesterol. Blood levels will be checked before starting treatment with selpercatinib and during treatment.

Rash

Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol-free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

Headache

Your healthcare provider can recommend medications and other strategies to help relieve pain.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Less common, but important side effects can include:

- *Heart Problems:*This medication can cause slow or abnormal heartbeats or an abnormal heart rhythm called QT prolongation. Notify your oncology care team right away if you feel abnormal heartbeats or if you feel dizzy or faint.
- **Bleeding:** Selpercatinib can cause abnormal bleeding. Contact your health care team immediately if you experience any bleeding, including: coughing up blood or blood clots, vomiting blood or if your vomit looks like coffee grounds, red or black stools, heavier than normal menstrual bleeding, or other unusual or heavy bleeding. If you experience symptoms of a stroke, you should contact your healthcare provider immediately or go to an emergency room. Symptoms can include: swelling, redness or pain in an extremity, chest pain or pressure, pain in your arm, back, neck or jaw, shortness of breath, numbness, or weakness on one side of the body, trouble talking, confusion or mental status changes.
- *Allergic Reactions*: In some cases, patients can have an allergic reaction to this medication. Signs of a reaction can include: Fever, rash, bone and joint aches/pain. Call your provider right away if you have any of these symptoms.
- *Wound healing*: This medication can lead to slower or incomplete wound healing, such as a surgical wound not healing or staying closed. Be sure to inform the team performing the surgical procedure that you are taking selpercatinib. You should also inform your oncology team if a surgical procedure is planned. It is recommended that this medication be discontinued at least 7 days prior to any surgery, and for at least 14 days after a surgery. In addition, any surgical incision should be fully healed prior to starting or restarting the medication. If you have a surgical wound that has not healed or begins to have signs of infection (redness, swelling, warmth), report this to your healthcare team.
- **Tumor Lysis Syndrome:** If there are a large amount of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given a medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.

Sexual & Reproductive Concerns

This medication may affect your reproductive system, resulting in the menstrual cycle or sperm production becoming irregular or stopping permanently. Women may experience menopausal effects including hot flashes and vaginal dryness. In addition, the desire for sex may decrease during treatment. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. For women, effective birth control is necessary during treatment and for at least 1 week after treatment. For men, effective birth control is necessary during treatment and for at least 1 week after treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication and for at least 1 week after the final dose.

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