

ORAL CHEMOTHERAPY EDUCATION



SELPERCATINIB

Name of your medication

Generic name — selpercatinib (SEL-per-KA-tih-nib)

Brand name — Retevmo™ (reh-TEV-moh)

Approved uses

Selpercatinib is used to treat non-small cell lung cancer (NSCLC) that has a genetic mutation called RET fusion.

Selpercatinib is used to treat thyroid cancer that has a genetic mutation or fusion in the RET protein.

Dose and schedule

Taking selpercatinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of selpercatinib is between 120 milligrams (120 mg) and 160 mg to be taken by mouth at a scheduled time twice a day.
- Your dose is based on many factors, including your height and weight, overall health, and diagnosis.
- Selpercatinib can be taken with or without food, but at the same time each day.
- Selpercatinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow selpercatinib, talk to your care provider or pharmacist for possible options.
- If you vomit a dose of selpercatinib, do not take another dose. Wait until your next scheduled dose.
- If you miss a dose of selpercatinib, follow these guidelines:
 - Do not take the missed dose unless it is more than 6 hours until your next scheduled dose. Simply take the next dose at the regularly scheduled time.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

Drug and food interactions

- Selpercatinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with selpercatinib; avoid eating or drinking these during treatment with selpercatinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle selpercatinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store selpercatinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep selpercatinib out of reach of children and pets.
- Leave selpercatinib in the provided packaging until it is ready to be taken.

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- Whenever possible, you should give selpercatinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the selpercatinib to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the selpercatinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder will be used, contact your care team before using.
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
- If you have any unused selpercatinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of selpercatinib.
- If you are traveling, put your selpercatinib's packaging in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Selpercatinib

Below are common side effects that have been known to happen in about one-third or more of patients taking selpercatinib; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Changes in liver function	Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following: <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
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Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values including</p> <ul style="list-style-type: none"> • Low calcium levels • High glucose levels • Low albumin levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Mouth irritation or sores or dry mouth</p>	<p>Practice good mouth care.</p> <ul style="list-style-type: none"> • Rinse your mouth frequently. • Brush your teeth with a soft toothbrush or cotton swab after meals. • Use a mild non-alcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. • If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p>

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Possible Side Effect	Management
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
<p>Changes in kidney function</p>	<p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Decreased amount of urination • Unusual swelling in your legs and feet
<p>Increased blood pressure</p>	<p>Routinely take your blood pressure. Record your blood pressure in a journal/diary, and report your findings to your physician. Contact your healthcare provider for high blood pressure or if symptoms such as the following occur:</p> <ul style="list-style-type: none"> • Headache • Dizziness • Chest pain • Shortness of breath • Fluid retention, weight gain, or swelling
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.

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Possible Side Effect	Management
Fluid retention or swelling	<ul style="list-style-type: none"> Do not stand for long periods of time. Keep your legs elevated when sitting or lying down. Avoid eating salty foods, which can increase swelling. Avoid wearing tight-fitting clothing and shoes. Weigh yourself daily. <p>Contact your care provider if you notice the following:</p> <ul style="list-style-type: none"> Swelling in the hands, feet, or legs Shortness of breath Weight gain of 5 pounds or more in a week
Decreased platelet count and increased risk of bleeding	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> Use caution to avoid bruises, cuts, or burns. Blow your nose gently, and do not pick your nose. Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene. When shaving, use an electronic razor instead of razor blades. Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include the following:</p> <ul style="list-style-type: none"> A bloody nose that bleeds for more than five minutes despite pressure A cut that continues to ooze despite pressure Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, observe blood in your urine or stool, cough up blood, or experience prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>
Increased cholesterol levels	<p>Changes in cholesterol may occur and will be monitored by a simple blood test.</p> <p>You may not feel any symptoms if changes occur. Your care team will monitor for this.</p>

Serious side effects

- ❑ Selpercatinib may be harmful to your liver. Seek medical attention if you notice yellowing of the skin or whites of your eyes, dark or brown urine, bleeding, or bruising.
- ❑ You may have high blood pressure while taking selpercatinib. Take your blood pressure on a regular basis, and let your care team know of any large increases in blood pressure.

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- Selpercatinib may cause a condition called QT or QTc prolongation, which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life-threatening. Tell your care team right away if you feel faint, lightheaded, or dizzy, or if you feel your heart beating irregularly or fast, while taking selpercatinib.
- You may be at a higher risk of bleeding while taking selpercatinib. Contact your care team if you notice frequent nose bleeds, blood in your stool, bleeding that occurs by itself without injury, or bleeding that will not stop after 5 minutes of pressure.
- Severe allergic reactions are a rare but serious side effect of selpercatinib. Immediately seek medical attention if you notice difficulty breathing, swelling of the mouth or tongue, or a serious rash.
- Selpercatinib can cause cuts or wounds to heal more slowly. Tell your care team if you have a wound that doesn't heal properly. Also tell your care team if you have a planned surgery or dental procedure, as selpercatinib should be stopped prior to your surgery. Your doctor may restart selpercatinib after your surgical wound has healed.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since selpercatinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take selpercatinib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or selpercatinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking selpercatinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 week after the last dose of selpercatinib.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.

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- Do not breastfeed while taking selpercatinib and for 1 week after the last dose of selpercatinib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

- Talk with your care provider about the process for obtaining your selpercatinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.retevmo.com>

Product prescribing information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213246s000lbl.pdf

Product resources: <https://www.retevmo.com/?section=savings-support>

Updated – May 27, 2020

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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