

Lenvatinib (Lenvima)

About This Medicine

Lenvatinib is used to treat cancer. It is given by orally (by mouth).

Possible Side Effects

- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Decreased appetite (decreased hunger)
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Tiredness
- Changes in your thyroid function
- Voice changes/hoarseness
- Weight loss
- Increased protein in your urine
- Bone, joint and muscle pain
- Headache
- Hand-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.
- High blood pressure

Note: Each of the side effects above was reported in 20% or greater of patients treated with lenvatinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Severe high blood pressure

- Changes in your heart function such as abnormal heartbeat, abnormal electrocardiogram (EKG/ ECG), and congestive heart failure - your heart is not pumping blood as well as it should be, and fluid can build up in your body. Some of these changes can be life-threatening.
- Blood clots and events such as stroke and heart attack. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.
- Changes in your liver function, which can cause liver failure and be life-threatening.
- Severe diarrhea
- Risk of gastrointestinal perforation or fistula – an abnormal hole in your stomach, intestine, esophagus, or other organ
- Changes in your thyroid function
- Changes in your kidney function, which can cause renal failure and be life-threatening.
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your doctor know right away.**
- Severe abnormal bleeding which can be life-threatening
- Severe decreased level of calcium in your blood
- Slow wound healing
- Osteonecrosis of the jaw. This is a breakdown of the jawbone. It is a serious but rare health problem.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- Lenvatinib may cause slow wound healing. It should not be given within at least 1 week of planned surgery/dental surgery and/or invasive dental procedures, and for at least 2 weeks and until adequate wound healing following major surgery. If you must have emergency surgery or have an accident that results in a wound, tell the doctor that you are on lenvatinib.

How to Take Your Medicine

- Swallow the medicine whole with or without food, at the same time each day. Do not crush or chew capsules.
- If you have trouble swallowing, you can dissolve up to 5 capsules at a time without breaking or crushing the capsules in 3 mL of water or apple juice. Put the capsules whole in the liquid using a container or an oral syringe (approximately 20 mL capacity) and let stand for at least 10 minutes for the capsule shell (outer surface) to dissolve completely. Stir or shake mixture for 3 minutes and drink the mixture. After drinking, add an additional 2 mL of water or apple juice to the container or oral syringe to rinse it, stir and drink the liquid right away. You may need to repeat this step to make sure all of the medicine is taken.
- If 6 capsules are required for your daily dose, follow the above instructions using 3 capsules at a time.



- **Missed dose:** If you miss a dose, take it as soon as you think about it. If it is within 12 hours of your next dose, then skip the missed dose. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store capsules in the original container at room temperature. Store the mixture in the refrigerator at 36°F to 46°F (2°C to 8°C) for a maximum of 24 hours. Throw away the mixture if not used within 24 hours of mixing.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have unused medicine take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- Tell your dentist and dental surgeon that you are taking this medicine. You should not have major dental surgery while on this medicine. See your dentist to have a dental exam and fix any dental problems before starting this medicine with your doctor's approval. Take good care of your teeth. Make sure you see your dentist for regular follow-up appointments.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.



- Include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- To help with decreased appetite, eat high calorie foods listed above and eat small, frequent meals.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Medicine Interactions

- There are no known interactions of lenvatinib with food.
- This medicine may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Headache that does not go away
- Confusion
- Extreme tiredness and/or coma
- Tiredness and/or weakness that interferes with your daily activities
- Blurry vision or changes in your eyesight
- Wheezing and/or trouble breathing
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or



sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**

- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Pain in your mouth and throat that makes it hard to eat or drink
- Difficulty swallowing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicine
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Pain in your abdomen that does not go away
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Signs of low calcium: numbness or tingling around your mouth or in your hands or feet, muscle stiffness, twitching, spasms, or cramps
- Signs of low thyroid function: tiredness, unexplained weight gain, hair loss, dry skin, constipation, increased sensitivity to cold
- Decreased or very dark urine
- Foamy or bubbly-looking urine
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling of your hands and/or feet
- Swelling in your legs, ankles, and/or feet
- Your leg is swollen, red, warm and/or painful
- Pain that does not go away, or is not relieved by prescribed medicines
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Signs of osteonecrosis of the jaw such as pain, swelling or infection of the gums, loose teeth, poor healing of the gums, numbness, or the feeling that your jaw is heavy
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Weight gain of 5 pounds in one week (fluid retention)
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 30 days after stopping treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 1 week after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.



- **Fertility warning:** In men and women both, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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