

## Lenvatinib (Lenvima)

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### About This Drug

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)
- Constipation (unable to move bowels)
- Pain in your abdomen
- Decreased appetite (decreased hunger)
- Abnormal bleeding
- Tiredness
- Swelling of your legs, ankles and/or feet
- Urinary tract infection
- Changes in your thyroid function
- Voice changes/hoarseness
- Weight loss
- Increased protein in your urine
- Bone, joint and muscle pain
- Headache
- Cough, trouble breathing
- Hand-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.
- Rash
- High blood pressure

**Note:** Each of the side effects above was reported in 20% or greater of patients treated with lenvatinib given in alone or in combination with other agents. Your side effects may be different depending on your specific condition. Not all possible side effects are included above.

### 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, which can be life-threatening.
- 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.**
- Abnormal bleeding which can be life-threatening – 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.
- 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 1 week of planned surgery 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 Medication

- Swallow the medicine whole with or without food, at the same time each day.
- If you have trouble swallowing, you can dissolve the capsules without breaking or crushing the capsules in 1 tablespoon of water or apple juice. Put the capsules whole in the liquid and let stand for at least 10 minutes. Stir for at least 3 minutes and drink the mixture. After drinking, add 1 tablespoon of water or apple juice to the glass to rinse it, stir and drink the liquid right away.
- **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. Instead, continue with your regular dosing schedule and contact your physician.



- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **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 medication label. Some facilities have unused medication 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.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- 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.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- Tell your dentist and dental surgeon that you are taking this drug. You should not have major dental surgery while on this drug. See your dentist to have a dental exam and fix any dental problems before starting this drug 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.



- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- 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 Drug Interactions

- There are no known interactions of lenvatinib with food.
- This drug 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
- Blurry vision or changes in your eyesight
- Cough that is bothersome
- 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
- No bowel movement in 3 days or when you feel uncomfortable
- 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.
- Decreased or very dark urine
- Foamy or bubbly-looking urine
- Signs of urinary tract infection such as a burning or pain when you pass urine, difficulty urinating, smelly and/or cloudy urine, pain in your lower abdomen or lower/side of your back
- Tiredness or weakness that interferes with your daily activities
- Unexplained weight gain
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- 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 drug 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 at least 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 at least 1 week after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug 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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