Lenvatinib (Lenvima®)

Pronounced: len-VA-ti-nib

Classification: Tyrosine Kinase Inhibitor

About Lenvatinib (Lenvima®)

Lenvatinib is a type of targeted therapy. This means it targets something specific to the cancer cells, therefore decreasing side effects caused by damage to the healthy cells. Lenvatinib works by blocking two processes that allow cancer cells to grow:

- Interfering with a protein that promotes cell division
- Blocking the VEGF receptor, which is responsible for angiogenesis, or the development of a blood supply to the tumor. This removes the tumor's source of nutrients.

How to Take Lenvatinib

Lenvatinib is available in capsule form that you take by mouth. The capsule should be swallowed whole or can be dissolved in water or apple juice. The dose you receive is dependent on cancer type and the treatment protocol. It can be taken with or without food and should be taken around the same time every day. If you miss a dose of lenvatinib, take it as soon as you remember. If the next dose is scheduled within 12 hours, skip the missed dose and take the next dose as regularly scheduled. Don't take an extra dose to make up for a missed dose.

To dissolve the capsules, measure 1 tablespoon of water or apple juice and put it in a cup with the capsules. Leave them in the liquid for 10 minutes, followed by stirring for 3 minutes. Drink the mixture and then add 1 tablespoon of water or apple juice to the glass, swirl the contents for a few moments and then drink the additional liquid.

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.

Lenvatinib can interact with certain medications. 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 pour 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?

Lenvatinib 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 without prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, are also available.

Possible Side Effects of Lenvatinib
There are a number of things you can do to manage the side effects of lenvatinib. 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:

**High Blood Pressure**
This medication can cause high blood pressure (hypertension). Patients should have their blood pressure checked 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.

**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 of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Muscle or Joint Pain/Aches and Headache**
Your oncology team can recommend medication and other strategies to relieve pain.

**Nausea and/or Vomiting**
Talk to your doctor or nurse 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 antacids, (e.g. milk of magnesia, calcium tablets such as Tums), saltines, or ginger ale to lessen symptoms.

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

**Mouth Ulcers (Mucositis)**
Certain cancer treatments can cause *sores or soreness in your mouth* and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing regular mouth care can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

**Bleeding**
This medication can cause serious, abnormal bleeding. It is important to notify your care provider if you have any excess bruising or bleeding, including nose bleeds, bleeding gums, headache, or blood in your urine or stool.

**Hand Foot Syndrome**

Hand foot syndrome (HFS) is a skin reaction that appears on the palms of the hands and/or the soles of the feet, as a result of certain chemotherapy agents being absorbed by the skin cells. HFS can begin as a mild tingling, numbness, pins-and-needles feeling, redness or pain or swelling of the hands and/or feet. This can then progress to painful swelling, blistering or peeling skin that can interfere with your ability to do normal activities. Be sure to let your oncology team know right away if you notice these symptoms, as they may need to adjust the chemotherapy dose or take a break to allow the skin to heal. Some tips to help prevent HFS include:

- Keep hands and feet clean and dry.
- Avoid tight shoes or socks.
- Avoid activities that put pressure on the palms or soles for 1 week after treatment.
- Apply an alcohol-free moisturizer liberally and often. (Avoid moisturizers with perfumes or scents)
- Avoid very hot water for baths and showers.

**Decrease in Appetite or Taste Changes**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Proteinuria**

This medication may cause proteinuria, the presence of protein in the urine. This can be a sign of kidney damage. Your oncology team will periodically check your urine for protein.

**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 lenvatinib. You should also inform your oncology team that a surgical procedure is planned. It is recommended that this medication be discontinued 6 days prior to any 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.

Less common, but important side effects can include:

- **Thyroid Hormone Levels:** This medication can impact levels of thyroid hormones. Your oncology care team will monitor these levels monthly and adjust thyroid replacement medication as needed.
- **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.
- **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. This medication can also decrease heart function. Notify your healthcare provider if you have sudden weight gain or swelling.
in the ankles or legs. If you develop chest pain or pressure, pain in the left arm, back, or jaw, sweating, shortness of breath, clammy skin, nausea, dizziness or lightheadedness, call 911 or go to the nearest emergency room.

- **Hypocalcemia**: Hypocalcemia is an electrolyte imbalance which is indicated by a low level of calcium in the blood. This medication can cause hypocalcemia. Your oncology team will periodically check your blood calcium levels while receiving this medication.

- **Liver Toxicity**: This medication can cause liver toxicity, which your doctor may monitor for using blood tests called liver function tests. If you develop elevations in your liver function tests, your healthcare provider may need to lower your dose or stop the medication. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown or pain in your abdomen, as these can be signs of liver toxicity.

- **Blood Clots**: This medication can cause blood clots. Blood clots can cause stroke, heart attack, deep vein thrombosis (DVT) or pulmonary embolism (PE). Symptoms 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. If you experience these symptoms, contact your healthcare provider immediately or go to an emergency room.

- **Gastrointestinal Side Effects**: This medication can cause bleeding or a tear in the intestinal wall. Signs of these problems include: unexpected bleeding, blood in the stool or black stools, coughing up blood, vomiting blood, vomit that looks like coffee grounds, fever, severe pain in the abdomen or new abdominal swelling. If you experience any of these, contact your healthcare provider immediately or go to the emergency room. Rarely, this medication can cause a fistula which is an abnormal connection between two body organs.

- **Posterior Reversible Encephalopathy Syndrome (PRES)**: In rare cases this medication has caused a neurological disorder called posterior reversible encephalopathy syndrome (PRES), also called reversible posterior leukoencephalopathy (RPLS). Symptoms of PRES/RPLS include headache, seizure, lethargy, confusion, blindness and other visual and neurological disturbances. Report any of these symptoms to your healthcare team immediately.

- **Osteonecrosis of the Jaw**: Osteonecrosis of the jaw (ONJ) is a rare side effect, however, it is important that you know about it and take steps to protect your dental health. The maxilla (upper jaw bone) and mandible (lower jaw bone) are normally covered by gum tissue. In the case of ONJ, this tissue is gone and the bone is exposed. Typical symptoms associated with ONJ are: pain, swelling or infection of the gums, loosenning of the teeth, exposed bone (often at the site of a previous tooth extraction or procedure). Some patients may report numbness or tingling in the jaw or a "heavy" feeling jaw. ONJ may have no symptoms for weeks or months and may only be recognized by the presence of exposed bone. ONJ most often occurs soon after a dental procedure, though not always. Stop treatment with "x" at least 3 weeks prior to any dental procedures.
  - Prior to starting therapy, you should have a complete dental exam, cleaning, and removal of any teeth in poor health.
  - Dentures should be checked for proper fit.
  - Brush your teeth after meals and at bedtime with a soft brush. Ask your care team if you are able to floss, and if you are, floss gently once a day.
  - Check your teeth and gums in a mirror daily for any sores, swelling, loose teeth, pain or numbness, or other changes and report these to your dentist or oncology team immediately.

**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. Effective birth control is necessary during treatment and for at least 30 days 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 lenvatinib and for one week after the final dose.
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