PATIENT INFORMATION
LENVIMA® (lehn-veema)
(lenvatinib)
capsules

What is LENVIMA?

LENVIMA is a prescription medicine that is used to treat adults with certain kinds of cancer.

- LENVIMA is used by itself to treat differentiated thyroid cancer (DTC), a type of thyroid cancer that has come back or spread, can no longer be treated with radioactive iodine, and is progressing.
- LENVIMA is used to treat a type of kidney cancer called advanced renal cell carcinoma (RCC):
  - in combination with the medicine pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph as your first treatment when your kidney cancer has spread or cannot be removed by surgery.
  - in combination with the medicine belzutifan to treat advanced RCC with a clear cell component following treatment with a type of anticancer medicine called a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1).
  - in combination with the medicine everolimus after one course of treatment with another anti-cancer medicine (anti-angiogenic therapy).
- LENVIMA is used by itself as the first treatment for a type of liver cancer called hepatocellular carcinoma (HCC) when it cannot be removed by surgery.
- LENVIMA is used in combination with the medicine pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph to treat advanced endometrial carcinoma (EC), a type of uterine cancer:
  - when a laboratory test shows that your tumor is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H), **and**
  - you have received anti-cancer treatment, and it is no longer working, **and**
  - your cancer cannot be cured by surgery or radiation.

The safety and efficacy of LENVIMA have not been established in children.

Before you take LENVIMA, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure
- have heart problems
- have a history of blood clots in your arteries (type of blood vessel), including stroke, heart attack, or change in vision
- have or have had liver or kidney problems
- have a history of a tear (perforation) in your stomach or intestine, or an abnormal connection between two or more body parts (fistula)
- have headaches, seizures, or vision problems
- have any bleeding problems
- plan to have surgery, a dental procedure, or have had a recent surgery. You should stop taking LENVIMA at least 1 week before planned surgery. See **"What are the possible side effects of LENVIMA?"**
- are pregnant or plan to become pregnant. LENVIMA can harm your unborn baby.

  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with LENVIMA.
  - Use an effective method of birth control (contraception) during treatment with LENVIMA and for 30 days after the last dose of LENVIMA. Talk with your healthcare provider about birth control methods you can use during

this time. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with LENVIMA.
    - If you are taking LENVIMA in combination with another medicine, your healthcare provider will tell you how long you should use birth control (contraception).
- are breastfeeding or plan to breastfeed. It is not known if LENVIMA passes into your breast milk. **Do not** breastfeed during treatment with LENVIMA and for 1 week after the last dose.
    - If you are taking LENVIMA in combination with another medicine, your healthcare provider will tell you how long you should not breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you are taking, or have taken, an osteoporosis medicine.

Know the medicines you take. Keep a list of your medicines to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take LENVIMA?

- Take LENVIMA exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much LENVIMA to take and when to take it.
- Take LENVIMA 1 time each day at the same time each day, with or without food.
- If you miss a dose of LENVIMA, take it as soon as you remember. If your next dose is due within 12 hours, skip the missed dose and take the next dose at your regular time.
- Swallow LENVIMA capsules whole**. Do not** crush or chew the LENVIMA capsules.
- If you cannot swallow LENVIMA capsules whole, LENVIMA capsules can be mixed with water or apple juice, then taken by mouth, or mixed with water and given through a feeding tube.
- If you take too much LENVIMA, call your healthcare provider or go to the nearest hospital emergency room right away.

How to take LENVIMA by mouth if you cannot swallow whole capsules:

- Place your daily dose, up to 5 capsules, in a small container or oral syringe (approximately 20 mL capacity).
- Add 3 mL of **water or apple juice** to the container or oral syringe. **Wait 10 minutes** for the capsule shell (outer surface) to dissolve completely, then stir or shake the mixture for 3 minutes until capsules are fully dissolved. **Do not** break or crush the capsules.
- Drink the liquid mixture or use an oral syringe to take directly into the mouth.
- Next, using a second syringe, add an additional 2 mL of liquid to the container or oral syringe (cap the first oral syringe before adding the additional water) then swirl or shake and take the liquid mixture. Repeat this step at least one time and until you cannot see any of the LENVIMA mixture left in the container or oral syringe 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.

How to give LENVIMA through a feeding tube:

- LENVIMA should be given in feeding tubes of at least 5 French diameter (polyvinyl chloride or polyurethane tube) and at least 6 French diameter (silicone tube).
    - Place your daily dose, up to 5 capsules, in a syringe (20 mL capacity).
    - Add 3 mL of **water** to the syringe. **Wait 10 minutes** for the capsule shell (outer surface) to dissolve completely, then stir or shake the mixture for 3 minutes until capsules are fully dissolved. Do not break or crush the capsules.
    - Give the mixture through a feeding tube.
    - Next, cap the syringe and remove the plunger. Use a second syringe and add an additional 2 mL of liquid to the syringe. Swirl or shake and give the mixture in the feeding tube. Repeat this step at least one time and until you cannot see any of the LENVIMA mixture left in the syringe 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.

- LENVIMA mixture may be stored in a covered container in the refrigerator at 36ºF to 46ºF (2ºC to 8ºC) for a maximum of 24 hours. Throw away the LENVIMA mixture if not used within 24 hours of mixing.

What are the possible side effects of LENVIMA?

LENVIMA may cause serious side effects, including:

- **High blood pressure (hypertension).** High blood pressure is a common side effect of LENVIMA and can be serious. Your blood pressure should be well controlled before you start taking LENVIMA. Your healthcare provider should check your blood pressure regularly during treatment with LENVIMA. Tell your healthcare provider if you get high blood pressure during treatment with LENVIMA. Your healthcare provider may prescribe medicine to treat your high blood pressure.
- **Heart problems.** LENVIMA can cause serious heart problems, including heart failure that may lead to death. Your healthcare provider will check your heart function before and during treatment with LENVIMA. Tell your healthcare provider right away if you get any signs or symptoms of heart problems, including:
  - shortness of breath
  - swelling of your ankles
  - unusual weight gain
  - chest pain
  - feeling faint
- **Problem with blood clots in your blood vessels (arteries).** Get emergency medical help right away if you get any of the following symptoms:
  - severe chest pain or pressure
  - pain in your arms, back, neck or jaw
  - shortness of breath
  - numbness or weakness on one side of your body
  - trouble talking
  - sudden severe headache
  - sudden vision changes
- **Liver problems.** LENVIMA may cause liver problems that may lead to liver failure and death. Your healthcare provider will check your liver function before and during treatment with LENVIMA. Tell your healthcare provider right away if you develop any of the following symptoms:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or tea colored urine
  - light-colored stools (bowel movements)
  - nausea or vomiting
  - pain in your upper right stomach area (abdomen)
  - feeling drowsy, confused, or losing consciousness
- **Kidney problems.** Kidney failure, which can lead to death, has happened with LENVIMA treatment. Your healthcare provider should do regular blood tests to check your kidneys. Tell your healthcare provider if you develop any signs and symptoms of kidney problem:
  - changes in the amount or color of your urine
  - blood in your urine
  - swelling in your legs or ankles
  - loss of appetite
- **Increased protein in your urine (proteinuria).** Proteinuria is a common side effect of LENVIMA and can be serious. Your healthcare provider should check your urine for protein before and during treatment with LENVIMA.
- **Diarrhea.** Diarrhea is a common side effect of LENVIMA and can be serious. If you get diarrhea, ask your healthcare provider about medicines you can take to treat your diarrhea. It is important to drink more water when you get diarrhea. Tell your healthcare provider or go to the emergency room if you are unable to drink enough liquids and your diarrhea cannot be controlled.
- **An opening in the wall of your stomach or intestines (perforation) or an abnormal connection between two or more body parts (fistula).** Get emergency medical help right away if you develop severe stomach area (abdomen) pain.

- **Changes in the electrical activity of your heart called QTc prolongation.** QTc prolongation can cause irregular heartbeats that can cause you to faint and may be life threatening. Your healthcare provider will do blood tests before and during your treatment with LENVIMA to check the salts (electrolytes) in your blood, including the levels of potassium, magnesium, and calcium, and may check the electrical activity of your heart with an electrocardiogram (ECG).
- **Low levels of blood calcium (hypocalcemia).** Your healthcare provider will check your blood calcium levels during treatment with LENVIMA and may tell you to take a calcium supplement if your calcium levels are low.
- **A condition called Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** Tell your healthcare provider right away if you get any of the following new or worsening symptoms:
  - severe headache
  - seizures
  - weakness
  - confusion
  - change in vision
- **Bleeding.** LENVIMA can cause serious bleeding problems that may lead to death. Tell your healthcare provider right away if you develop any signs or symptoms of bleeding during treatment with LENVIMA, including:
  - severe and persistent nose bleeds
  - vomiting blood
  - red or black (looks like tar) stools
  - blood in your urine
  - coughing up blood or blood clots
  - heavy or new onset vaginal bleeding
- **Change in thyroid hormone levels**. Your healthcare provider should check your thyroid hormone levels before starting and every month during treatment with LENVIMA.
- **Wound healing problems.** Wound healing problems have happened in some people who take LENVIMA. Tell your healthcare provider if you plan to have any surgery before or during treatment with LENVIMA.
  - You should stop taking LENVIMA at least 1 week before planned surgery.
  - Your healthcare provider should tell you when you may start taking LENVIMA again after surgery.
- **Severe jawbone problems (osteonecrosis).** Severe jawbone problems have happened in some people who take LENVIMA. Certain risk factors such as taking a bisphosphonate medicine or the medicine denosumab, having dental disease, or an invasive dental procedure may increase your risk of getting jawbone problems. Your healthcare provider should examine your mouth before you start and during treatment with LENVIMA. Tell your dentist that you are taking LENVIMA. It is important for you to practice good mouth care during treatment with LENVIMA. Tell your healthcare provider right away if you get signs or symptoms of jawbone problems during treatment with LENVIMA, including jaw pain, toothache, or sores on your gums. Tell your healthcare provider if you plan to have any dental procedures before or during treatment with LENVIMA. You should avoid having invasive dental procedures if possible, during treatment with LENVIMA. Stopping your bisphosphonate medicine before an invasive dental procedure may help decrease your risk of getting these jaw problems.
  - You should stop taking LENVIMA at least 1 week before planned dental surgery or invasive dental procedures.
  - Your healthcare provider should tell you when you may start taking LENVIMA again after dental procedures.

The most common side effects of LENVIMA in adults treated for thyroid cancer include:

- tiredness
- joint and muscle pain
- decreased appetite
- weight loss
- nausea
- mouth sores
- headache
- vomiting
- rash, redness, itching, or peeling of your skin on your hands and feet
- stomach area (abdomen) pain
- hoarseness

The most common side effects of LENVIMA in adults treated for liver cancer include:

- tiredness
- decreased appetite
- joint and muscle pain
- weight loss
- stomach area (abdomen) pain
- rash, redness, itching, or peeling of your skin on your hands and feet
- hoarseness
- bleeding
- decreased thyroid hormone levels (hypothyroidism)
- nausea

The most common side effects of LENVIMA in adults treated for kidney cancer in combination with pembrolizumab include:

- tiredness
- joint and muscle pain
- decrease in thyroid hormone levels
- mouth sores
- decreased appetite
- rash
- nausea
- weight loss
- hoarseness
- rash, redness, itching, or peeling of your skin on your hands and feet
- stomach area (abdomen) pain
- bleeding
- vomiting
- constipation
- liver problems
- headache
- sudden kidney injury

The most common side effects of LENVIMA in adults treated for endometrial cancer in combination with pembrolizumab include:

- decrease in thyroid hormone levels
- tiredness
- joint and muscle pain
- nausea
- decreased appetite
- vomiting
- mouth sores
- weight loss
- stomach area (abdomen) pain
- urinary tract infection
- constipation
- headache
- bleeding
- rash, redness, itching, or peeling of your skin on your hands and feet
- hoarseness
- rash

The most common side effects of LENVIMA in adults treated for kidney cancer in combination with belzutifan include:

- decreased red blood cell counts
- tiredness
- muscle and joint pain
- nausea
- decrease in thyroid hormone levels
- decreased appetite
- rash
- vomiting
- weight loss
- constipation
- stomach area (abdomen) pain
- mouth sores

The most common side effects of LENVIMA in adults treated for kidney cancer in combination with everolimus include:

- tiredness
- joint and muscle pain
- decreased appetite
- vomiting
- nausea
- mouth sores
- swelling in your arms and legs
- cough
- stomach area (abdomen) pain
- trouble breathing
- rash
- weight loss
- bleeding

Your healthcare provider may reduce your dose of LENVIMA, delay or completely stop treatment, if you have certain side effects.

LENVIMA may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of LENVIMA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LENVIMA?

- Store LENVIMA at room temperature, between 68°F to 77°F (20°C to 25°C).

Keep LENVIMA and all medicines out of the reach of children.

General information about the safe and effective use of LENVIMA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LENVIMA for a condition for which it was not prescribed. Do not give LENVIMA to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about LENVIMA that is written for health professionals.

What are the ingredients in LENVIMA?

Active ingredient: lenvatinib

Inactive ingredients: calcium carbonate, hydroxypropyl cellulose, low-substituted hydroxypropylcellulose, mannitol, microcrystalline cellulose, and talc.

The capsule shell contains: ferric oxide red, ferric oxide yellow, hypromellose, and titanium dioxide. The printing ink contains black iron oxide, potassium hydroxide, propylene glycol and shellac.

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For more information, call 1-877-873-4724 or go to www.LENVIMA.com.

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