Your guide to LENVIMA®

What is LENVIMA?
LENVIMA (lenvatinib) is a prescription medicine that is used to treat certain kinds of cancer.

Thyroid cancer
LENVIMA is used by itself to treat differentiated thyroid cancer (DTC), a type of thyroid cancer that can no longer be treated with radioactive iodine and is progressing.

Kidney cancer
LENVIMA is used along with another medicine called everolimus to treat advanced renal cell carcinoma (RCC), a type of kidney cancer, after one course of treatment with another anti-cancer medicine.

It is not known if LENVIMA is safe and effective in children.

Selected Safety Information

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. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure, lower your dose of LENVIMA, or stop your treatment with LENVIMA.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.
Contact information

Keep track of helpful information below if you have already been prescribed LENVIMA.

Your next appointment date and time: _______________________
__________________________________________________________
__________________________________________________________

Your doctor’s name and phone number: _______________________
__________________________________________________________
__________________________________________________________

Your nurse’s name and phone number: _______________________
__________________________________________________________
__________________________________________________________

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Please see Selected Safety Information throughout and accompanying full Prescribing Information.
LENVIMA® and thyroid cancer

Differentiated thyroid cancer (DTC), including papillary and follicular (including Hürthle cell) carcinoma, is a type of thyroid cancer that is commonly treated with radioactive iodine (RAI) therapy. RAI works by concentrating in thyroid cells and destroying the thyroid tissue and any other thyroid cells (including cancer cells) that take up iodine. Sometimes you may no longer be able to receive RAI. This could happen if:

› your tumors are not taking up RAI
› your tumors take up RAI, but the cancer is getting worse or
› you have received a lifetime total RAI dose of >600 mCi (22 GBq)

Progression is when your cancer gets worse or spreads over time. Sometimes, progression may make your symptoms feel worse, while other times you may not feel new or worsening symptoms at first. It is important to talk to your doctor so he/she can perform scans to confirm if your cancer is progressing.

LENVIMA is a prescription medicine used to treat people with DTC that is progressing and can no longer be treated with RAI.

How was LENVIMA studied in patients with DTC?

LENVIMA was studied in a clinical trial of 392 patients with DTC that

› was progressing and
› could no longer be treated with RAI

In this trial, patients were randomly assigned to receive either LENVIMA or placebo.

Patients treated with LENVIMA lived without their cancer getting worse for an average of 18.3 months (some longer and some not as long). Patients who received placebo lived without their cancer getting worse for an average of 3.6 months (some longer and some not as long). This means that patients taking LENVIMA lived without their cancer getting worse for an average of 14.7 months longer than those not taking LENVIMA.

Selected Safety Information

› LENVIMA may cause serious side effects, including heart problems: LENVIMA can cause serious heart problems that may lead to death. Call your healthcare provider right away if you get symptoms of heart problems, such as shortness of breath or swelling of your ankles.

Talk to your doctor to see if LENVIMA may be right for you.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.
Advanced renal cell carcinoma (RCC) is a type of kidney cancer. When advanced RCC is not able to be treated with surgery, your doctor will usually prescribe a medicine that targets the tumor. If this first treatment does not work or stops working, you may need a second treatment.

LENVIMA is used with another medicine, everolimus, to treat advanced RCC.

**Talk to your doctor to see if LENVIMA may be right for you.**

**How was LENVIMA studied in patients with advanced RCC?**

LENVIMA was studied in a clinical trial of 153 patients with advanced RCC that

- could no longer be treated with surgery
- was advanced or spreading
- and
- was already treated with 1 prior medicine

In this trial, patients were randomly assigned to receive either LENVIMA and everolimus, LENVIMA by itself, or everolimus by itself.

Patients treated with LENVIMA and everolimus together lived without their cancer getting worse for an average of 14.6 months (some longer and some not as long). Patients who received everolimus by itself lived without their cancer getting worse for an average of 5.5 months (some longer and some not as long). This means that patients taking LENVIMA and everolimus together lived without their cancer getting worse for an average of 9.1 months longer than patients who only took everolimus.

**Selected Safety Information**

- **LENVIMA may cause serious side effects, including 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.
What should I tell my health care provider before taking LENVIMA®?

Before you take LENVIMA, tell your health care provider 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 kidney or liver problems
- have a history of a tear (perforation) in your stomach or intestine, or an abnormal connection between 2 parts of your gastrointestinal tract (fistula)
- have headaches, seizures, or vision problems
- have any bleeding problems

- are pregnant or plan to become pregnant. LENVIMA can harm your unborn baby
  - Females who are able to become pregnant should use an effective method of birth control during treatment with LENVIMA and for at least 2 weeks after the last dose of LENVIMA. Talk with your health care provider about birth control methods you can use during this time
  - Tell your health care provider right away if you become pregnant or think you are pregnant during treatment with LENVIMA
- are breastfeeding or plan to breastfeed. It is not known if LENVIMA passes into your breast milk. Do not breastfeed during treatment with LENVIMA

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

Know the medicines you take. Keep a list of your medicines to show to your health care provider and pharmacist when you get a new medicine.
How should I take LENVIMA®?

› Take LENVIMA exactly as your health care provider tells you to take it.

› LENVIMA capsules come in 2 strengths:

  Capsule imprint: € LENV 10 mg  
  Capsule imprint: € LENV 4 mg

Capsules pictured are not actual size.
Everolimus tablet for RCC not pictured.

› Your health care provider will tell you how much LENVIMA to take and when to take it. Your health care provider may change your dose during treatment, stop treatment for some time, or completely stop treatment with LENVIMA if you have side effects.

Selected Safety Information

› LENVIMA may cause serious side effects, including 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 have any of the following symptoms: your skin or the white part of your eyes turns yellow (jaundice); dark, “tea-colored” urine; light-colored bowel movements (stools); feeling drowsy, confused, or loss of consciousness.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

› Take LENVIMA 1 time each day at the same time, 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.

› If you cannot swallow LENVIMA capsules whole:
  — use a medicine cup to measure about 1 tablespoon of water or apple juice and place into a small glass
  — place the LENVIMA capsules into the small glass without breaking or crushing them
  — leave the capsules in the liquid for at least 10 minutes
  — stir the contents of the glass for at least 3 minutes
  — drink the mixture. After drinking, rinse the glass with a small amount of additional water or apple juice and swallow the liquid.

› If you take too much LENVIMA, call your health care provider or go to the nearest hospital emergency room right away.

For patients with RCC

Please also consult the everolimus Prescribing Information or talk to your health care team to learn how to take everolimus in combination with LENVIMA.
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. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure, lower your dose of LENVIMA, or stop your treatment with LENVIMA.

- **Heart problems:** LENVIMA can cause serious heart problems that may lead to death. Call your healthcare provider right away if you get symptoms of heart problems, such as shortness of breath or swelling of your ankles.

- **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 have any of the following symptoms: your skin or the white part of your eyes turns yellow (jaundice); dark, “tea-colored” urine; light-colored bowel movements (stools); feeling drowsy, confused, or loss of 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.

- **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 your treatment with LENVIMA. If you develop protein in your urine, your healthcare provider may decrease your dose of LENVIMA or stop your treatment.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

(Continued on the next page.)
What are the possible side effects of LENVIMA®?

- **diarrhea:** Diarrhea is a common side effect of LENVIMA and can be serious. If you get diarrhea, ask your healthcare provider about what 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 is not able to 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 have severe stomach (abdomen) or chest pain.

- **changes in the electrical activity of your heart called QT prolongation:** QT prolongation can cause irregular heartbeats that can be life threatening. Your healthcare provider will do blood tests before and during your treatment with LENVIMA to check the levels of potassium, magnesium, and calcium in your blood, and may check the electrical activity of your heart with an 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.

- **bleeding:** LENVIMA may cause serious bleeding problems that may lead to death. Tell your healthcare provider if you have 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:** You may have changes in your thyroid hormone levels when taking LENVIMA. Your healthcare provider may need to change your dose of thyroid medicine while you are taking LENVIMA. Your healthcare provider should check your thyroid hormone levels before starting and every month during treatment with LENVIMA.

- **wound healing problems:** If you need to have a surgical procedure, tell your healthcare provider that you are taking LENVIMA. LENVIMA should be stopped until your wound heals.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

(Continued on the next page.)
What are the possible side effects of LENVIMA®?

The most common side effects of LENVIMA in people 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 (abdomen) pain; and hoarseness.

The most common side effects of LENVIMA in people treated for kidney cancer include tiredness, joint and muscle pain, decreased appetite, vomiting, nausea, mouth sores, swelling in your arms and legs, cough, stomach (abdomen) pain, trouble breathing, rash, weight loss, and bleeding.

The most common side effects of LENVIMA in people treated for liver cancer include tiredness; decreased appetite; joint and muscle pain; weight loss; stomach (abdomen) pain; rash, redness, itching, or peeling of your skin on your hands and feet; hoarseness; bleeding; change in thyroid hormone levels; nausea.

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 the FDA at 1-800-FDA-1088.

How should I store LENVIMA?

- Store LENVIMA at room temperature, between 68°F and 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.

If you would like more information, talk with your health care provider. You can ask your health care provider or pharmacist for information about LENVIMA that is written for health professionals.

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

Please see Selected Safety Information throughout and accompanying full Prescribing Information.
**Financial support**

You may be eligible for the LENVIMA $0 Co-pay Program, which offers commercially insured patients a $0 co-pay for each prescription, with a $40,000 annual limit.* No activation is required.

Eisai, the maker of LENVIMA, is committed to providing assistance to you for access and reimbursement issues.

The Eisai Assistance Program can help you

- understand how your therapy may be covered by your insurance
- understand your coverage options if you do not have commercial insurance or are uninsured
- learn more about out-of-pocket costs for your treatment
- determine eligibility for assistance if you are unable to afford your medication

For more information about LENVIMA financial assistance that may be available, contact your Specialty Pharmacy.

For additional assistance, contact the Eisai Assistance Program at www.LenvimaReimbursement.com or by calling 1-866-61-EISAI (1-866-613-4724).

*Restrictions apply.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

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**How will I receive LENVIMA?**

LENVIMA is an oral medication that is available through two Specialty Pharmacies (Accredo and Biologics) or through select clinics and hospital pharmacies. These pharmacies will assist you from the start of therapy and will be in regular contact with you throughout your treatment. Your health care team will share with you how you will receive LENVIMA.

If you are receiving LENVIMA through Accredo or Biologics, you will receive your prescription via mail. It is important to know the name and contact information of your pharmacy so that you can respond promptly to their phone calls and communications.

**accredo**

www.accredo.com
Phone: 1-844-693-0156
Fax: 1-877-247-4847

If you are receiving LENVIMA from a select clinic or hospital pharmacy, it will be provided locally by your health care team. Reimbursement assistance can be accessed through the Eisai Assistance Program. Please contact 1-866-61-EISAI (1-866-613-4724) for more information.
Please see Selected Safety Information throughout and accompanying full Prescribing Information.