

Actor portray

YOUR GUIDE TO TAKING

LENVIMA® and everolimus for advanced renal cell carcinoma (RCC)

LENVIMA is used to treat adults with a type of kidney cancer called advanced RCC along with the medicine everolimus after one course of treatment with another anticancer medicine (anti-angiogenic therapy).

The safety and efficacy of LENVIMA have not been established 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

Please see Selected Safety Information throughout and on pages 13-15, and full Prescribing Information in pocket.



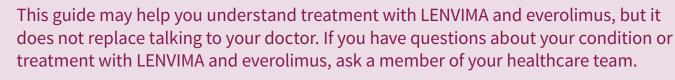


Being diagnosed with cancer can be an overwhelming experience. Each stage of your disease is different. So is the treatment for it.

Because you have already gotten at least one course of treatment with another anticancer medicine (anti-angiogenic therapy) for your kidney cancer, your doctor believes that at this stage of treatment, LENVIMA® and everolimus may be right for you. You can take it at home once a day.

This guide is made to help you:

- better understand this type of kidney cancer
- better understand what you may expect from your treatment with LENVIMA and everolimus
- learn about support that may be available to you



This guide should only be used if you have been prescribed LENVIMA and everolimus for advanced renal cell carcinoma (RCC), a type of kidney cancer.

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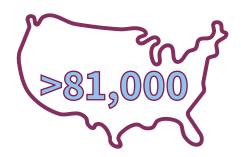
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Understanding kidney cancer

Cancer is a disease in which cells in the body grow out of control. Cancer that starts in the kidney is called kidney cancer.

Kidney cancer is more common than you think...



It is estimated that about **81,000 people** in the United States **will be diagnosed** with kidney cancer in **2024** alone.



The average age of people when they are diagnosed with kidney cancer is 64.

SELECTED SAFETY INFORMATION

LENVIMA® may cause serious side effects, including (cont'd):

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



Renal cell carcinoma, or RCC, is the most common type of kidney cancer in adults. About 9 out of 10 kidney cancers are RCC.



Advanced RCC is a type of kidney cancer. If you have been given treatment for advanced RCC and it does not work or stops working, you may need a second treatment



LENVIMA is used with another medicine, everolimus, to treat advanced RCC after one prior anticancer treatment (anti-angiogenic therapy) that is no longer helping



Please consult the everolimus Prescribing Information or talk to your healthcare team to learn how to take everolimus in combination with LENVIMA.





What is LENVIMA® and how is it thought to work?

Understanding what LENVIMA is can help you in your journey. LENVIMA is used to treat adults with RCC along with the medicine everolimus after one course of treatment with another anticancer medicine (anti-angiogenic therapy).



LENVIMA isn't chemotherapy. It's an oral medicine known as a targeted therapy. It is called that because it targets certain proteins on cancer cells that cause the cells to grow and multiply. Since healthy cells also contain these proteins, LENVIMA affects some healthy cells, which may cause serious side effects.

How LENVIMA is thought to work



Cancer cells send out signals that tell the body to make more blood vessels

LENVIMA is believed to interfere with some signals that allow cancer cells to grow and multiply



The cancer uses these new **blood vessels** to grow and spread

LENVIMA is also thought to impair some of the activities blood vessels need to grow. Blood vessels support the tumor's survival and growth

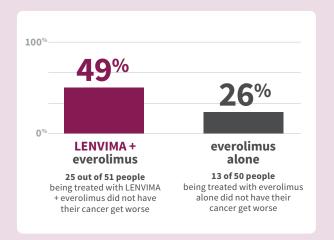
Please consult the everolimus Prescribing Information or talk to your healthcare team to learn how to take everolimus in combination with LENVIMA.

How can LENVIMA and everolimus help patients with advanced RCC?

The combination treatment LENVIMA + everolimus was studied in a clinical trial of 153 people with advanced or metastatic RCC who were treated with one previous anticancer medicine (anti-angiogenic therapy) as compared to everolimus alone.

A clinical study of LENVIMA + everolimus showed:

LENVIMA taken with everolimus was shown to help some people with advanced or metastatic RCC to continue living without their cancer getting worse. 49% (25 out of 51 people) of people taking LENVIMA + everolimus stayed alive without their cancer getting worse compared to 26% (13 out of 50 people) taking everolimus alone at the time of follow-up.





was the median* time people treated with LENVIMA + everolimus together did not have their cancer get worse compared to 5.5 months for those treated with everolimus alone.



As with all medicines, LENVIMA may come with some side effects. **Side effects can impact each person differently, but there may be ways to manage them.** Tell your healthcare team right away about any side effects you develop so they can consider the best management options.



^{*}A median is the middle number in a list of numbers arranged from lowest to highest.

What should I tell my healthcare team before taking LENVIMA®?

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

are pregnant or plan to become pregnant.
 LENVIMA can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with LENVIMA
- You should use an effective method of birth control 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
- 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

TIPS!

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?

LENVIMA should be taken 1 time each day at the same time, with or without food

Your healthcare provider will tell you how much LENVIMA to take and when to take it. Your healthcare provider may also adjust your dose during treatment, stop treatment for some time, or completely stop treatment with LENVIMA if you have side effects. Please consult the everolimus Prescribing Information or talk to your healthcare team to learn how to take everolimus in combination with LENVIMA.

There are 3 ways to take LENVIMA



Capsules pictured are not actual size. See instructions for preparation starting on page 10.



What if I miss a dose?

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.



What if I take too much?

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



How can I take LENVIMA® if I can't swallow whole capsules?



Place your daily dose, up to 5 capsules, in a small container or oral syringe (approximately 20-mL capacity)



Drink the liquid mixture or use an oral syringe to take directly into the mouth



Add 3 mL of water or apple juice to the container or oral syringe



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



(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

Wait 10 minutes for the capsule shell



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 can LENVIMA be taken 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



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



How should I store LENVIMA®?



Store LENVIMA in a room with a **steady temperature**, between 68 °F and 77 °F (20 °C and 25 °C).



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

General information about the safe and effective use of LENVIMA

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.



Selected Safety Information

Side effects are possible when you take LENVIMA, and some can be serious. It's important to talk with your doctor about any side effects because there are steps that can be taken to help manage them. Your doctor can help you decide what might work best for you.

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

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 develop 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

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



Selected Safety Information (continued)

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 (abdomen) 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 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): Call your healthcare provider right away if you get severe headache, seizures, weakness, confusion, or blindness or change in vision

bleeding: LENVIMA may cause serious bleeding problems that may lead to death. Tell your healthcare provider 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 jaw bone problems (osteonecrosis): Severe jaw bone 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 jaw bone 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 have any signs or symptoms of jaw bone problems during treatment with LENVIMA, including jaw pain, toothache, or sores on your gums and if you plan to have any dental procedures before or during treatment with LENVIMA.

- 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 people 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 (abdomen) pain, trouble breathing, rash, weight loss, and bleeding.

Selected Safety Information (continued)

LENVIMA may cause fertility problems in males and females and can harm your unborn baby. Tell your healthcare provider if you are:

- pregnant or plan to become pregnant. For females who are able to become pregnant, your healthcare provider should 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
- 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

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

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 or visit www.fda.gov/medwatch.

For more information about LENVIMA, please see full Prescribing Information.

Talk to your doctor about any side effects you may experience. For tips on managing certain side effects, visit **www.LENVIMA.com/treatment-tips** or scan the QR code here with your smartphone.





Help with affording LENVIMA®

There are available options to help you pay for LENVIMA if you are eligible.

These resources may help:

Eisai Patient Support

If you need further information or help paying for LENVIMA, Eisai Patient Support may be able to help. Contact Eisai Patient Support directly at **1-866-613-4724**.

Eisai Patient Support is your resource for information about coverage of LENVIMA and available financial assistance options. It will help you:

- Determine your insurance coverage for LENVIMA and where to access your medication
- Manage your out-of-pocket costs for LENVIMA and determine eligibility for assistance if you cannot afford your medication

LENVIMA Co-Pay Program

With the LENVIMA Co-Pay Program, eligible commercially insured people may pay as little as \$0 per month.* Annual limits apply. Depending on your insurance plan, you could have additional financial responsibility.

See www.LENVIMAREIMBURSEMENT.com for complete terms and conditions.

*Not available to people enrolled in state or federal healthcare programs, including Medicare, Medigap, VA, DoD, or TRICARE



Visit www.LENVIMAREIMBURSEMENT.com for more information

Phone: **1-866-61-EISAI** (1-866-613-4724) Fax: 1-855-246-5192 8 AM to 8 PM ET Monday through Friday

Please note that the link above leads to an English-only website. The phone number provided is staffed with an English-speaking representative. An interpreter who speaks your preferred language can be provided if needed.

Eisai cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. For additional information, customers should consult with their payers for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record.



You can receive LENVIMA through:

- Certain specialty pharmacies
- Select eligible physician offices or clinics
- Select eligible hospital pharmacies

Specialty Pharmacies

LENVIMA is available through certain specialty pharmacies, which will mail the medication directly to people.

Please visit www.LenvimaSpecialtyPharmacy.com for a complete list of the mail-order specialty pharmacies that dispense LENVIMA.



Please note many specialty pharmacies may also be **staffed with an interpreter** who speaks your preferred language.

Please ask the English-speaking representative for an interpreter.



Symptom Tracker

Record each symptom and how severe it is on a scale of 1 (mild) to 4 (very severe). Share your notes at your next visit with your healthcare provider. Write down suggestions from your healthcare provider that may help manage your symptoms.

However, don't forget to contact your healthcare provider right away if you start to feel any new or worsening symptoms or side effects, or have any questions.

Date	Describe any symptoms you're experiencing	Healthcare provider's suggestions	Additional notes
		,	•
	How severe? (circle one) 1 mild 2 moderate 3 severe 4 very severe		
Date	Describe any symptoms you're experiencing	Healthcare provider's suggestions	Additional notes
	How severe? (circle one) 1 mild 2 moderate 3 severe 4 very severe		
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Date	Describe any symptoms you're experiencing	Healthcare provider's suggestions	Additional notes
	How severe? (circle one) 1 mild 2 moderate 3 severe 4 very severe		





Learn more at www.LENVIMA.com



You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088**.

Please see Selected Safety Information throughout and on pages 13-15, and full Prescribing Information in pocket.

