

Your guide to taking LENVIMA[®] and everolimus for advanced renal cell carcinoma (RCC), a type of kidney cancer

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.

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



Please see Selected Safety Information throughout and on pages 14-17 and full [Prescribing Information](#).

**YOU ARE
NOT ALONE.
WE ARE
HERE TO
SUPPORT YOU.**

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 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 was designed to help you get started on treatment with LENVIMA and everolimus.

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 may help you understand treatment with LENVIMA and everolimus, but it does not replace talking to your doctor. If you have questions about your condition or treatment with LENVIMA and everolimus, ask a member of your healthcare team.

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

TABLE OF CONTENTS

Understanding kidney cancer	4
Understanding RCC	5
What is LENVIMA and how is it thought to work?	6
How can LENVIMA and everolimus help patients with advanced RCC?	7
What should I tell my healthcare team before taking LENVIMA?	8
How should I store LENVIMA?	9
How should I take LENVIMA?	10
How can I take LENVIMA if I can't swallow whole capsules?	12
How can LENVIMA be taken through a feeding tube?	13
Financial support	18
Filling your LENVIMA prescription.	19
Contact information and questions to ask your healthcare team	20



UNDERSTANDING KIDNEY CANCER

UNDERSTANDING RCC

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...



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



It is estimated that about 79,000 people in the United States will be diagnosed with kidney cancer in 2022 alone.

Renal cell carcinoma, or RCC, is the most common type of kidney cancer. 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 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?

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

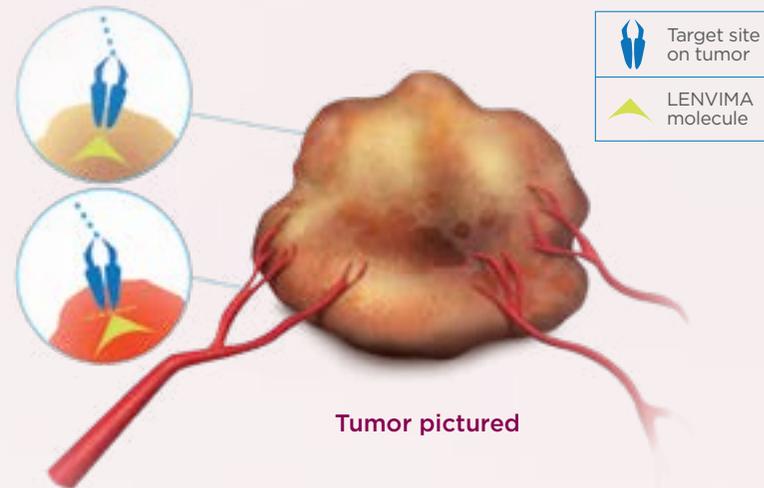
HOW LENVIMA IS THOUGHT TO WORK

Cells

LENVIMA is believed to block some signals that allow the cells (tumor and healthy) to survive and multiply.

Blood vessels

LENVIMA is believed to block some signals that help blood vessels grow. Blood vessels support the tumor's survival and growth.



LENVIMA is a targeted treatment. 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.

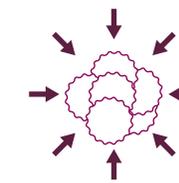
Please consult the everolimus Prescribing Information or talk to your healthcare team to learn how to take everolimus in combination with LENVIMA.

HOW CAN LENVIMA AND EVEROLIMUS HELP PATIENTS WITH ADVANCED RCC?

LENVIMA was studied in a phase 2 clinical trial of 153 patients with RCC that was advanced or spreading and was already treated with one prior anticancer medicine vs everolimus alone.

MORE THAN 2X AS LONG

People treated with LENVIMA + everolimus together **did not have their cancer get worse for more than twice as long (9.1 months longer) as patients receiving everolimus alone, with some living longer and some not as long**—median* 14.6 months with LENVIMA + everolimus (51 people) vs median 5.5 months with everolimus alone (50 people).



37% (19 of 51 people) taking LENVIMA + everolimus had their tumors shrink (with 35% of people [18 on LENVIMA vs 3 on everolimus] showing some signs of disease and 2% of people [1 on LENVIMA vs 0 on everolimus] showing no signs of disease) compared with 6% (3 of 50 people) taking everolimus alone.



This trial proved that treatment with LENVIMA + everolimus may benefit some patients with advanced RCC who were already treated with one prior anticancer medicine.

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

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



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



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 STORE LENVIMA?



77°F
68°F

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



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

- Be sure to store LENVIMA in a room with a steady temperature

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.



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.

There are 3 ways to take LENVIMA

 Swallow capsules whole	 Mix with water or apple juice	 Prepare suspension for feeding tube administration with water
---	--	--

Capsules pictured are not actual size.

See instructions for preparation starting on page 12

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?

1. Place your daily dose, up to 5 capsules, in a small container or oral syringe (approximately 20 mL capacity)
2. Add 3 mL of water or apple juice to the container or oral syringe
3. 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
4. Drink the liquid mixture or use an oral syringe to take directly into the mouth
5. 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
6. 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.

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 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).

1. Place your daily dose, up to 5 capsules, in a syringe (20 mL capacity)
2. 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
3. Give the mixture through a feeding tube
4. 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.

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.

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
- **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
- **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) 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
- **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 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

SELECTED SAFETY INFORMATION

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

- **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

SELECTED SAFETY INFORMATION

The most common side effects of LENVIMA when given with everolimus in people treated with 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
- bleeding

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 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.



Talk to your doctor about any side effects you may experience

 **LENVIMA®**
(lenvatinib) capsules | 10 mg and 4 mg

FINANCIAL SUPPORT

If you and your doctor decide that LENVIMA® is the right medicine for you, Eisai has resources that may help.

There may be assistance available for eligible patients:

- Who are uninsured
- Who don't know if they can afford their capsules
- Who don't know if they can pay their insurance co-pay

Eisai Assistance Program

- Understand how your therapy may be covered by your insurance*
- Learn more about out-of-pocket costs for your treatment
- Determine eligibility for assistance if you cannot afford your medication



Phone: 1-866-61-EISAI (1-866-613-4724)

Fax: 1-855-246-5192

**Hours: 8 AM to 8 PM ET,
Monday through Friday**

www.LenvimaReimbursement.com

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.

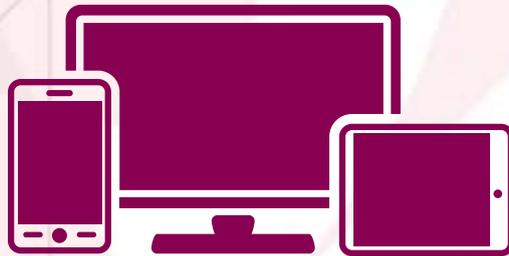
FILLING YOUR LENVIMA PRESCRIPTION

Specialty Pharmacies

LENVIMA is available through certain Specialty Pharmacies, which will mail the medication directly to patients. Please visit www.LenvimaSpecialtyPharmacy.com for a complete list of the mail-order Specialty Pharmacies that dispense LENVIMA.

Physician office/clinic or hospital pharmacies

LENVIMA can also be dispensed through eligible physician offices, clinics or hospital pharmacies. Please contact your preferred distributor for more information, including eligibility requirements.



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 14-17 and full [Prescribing Information](#).



LENVIMA® is a registered trademark used by Eisai Inc. under license from Eisai R&D Management Co., Ltd.
© 2023 Eisai Inc. All rights reserved. June 2023 LENV-US9157

