

Your guide to taking LENVIMA[®] for hepatocellular carcinoma (HCC), a type of liver cancer

LENVIMA is a prescription medicine that 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.

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

**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 a type of liver cancer that can't be treated with surgery, your doctor believes that at this stage of treatment, LENVIMA® 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.

This guide is made to help you:

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

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

This guide should only be used if you have been prescribed LENVIMA for inoperable liver cancer.

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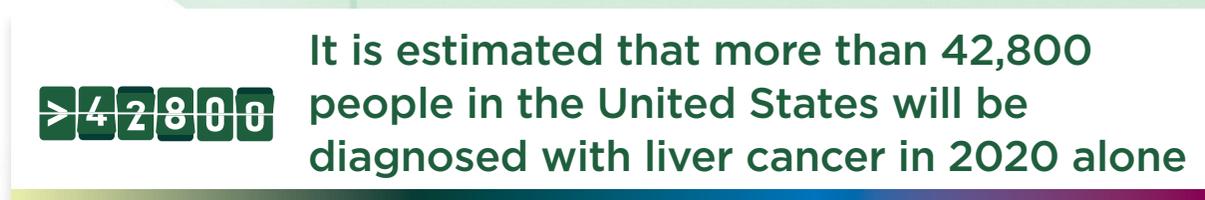
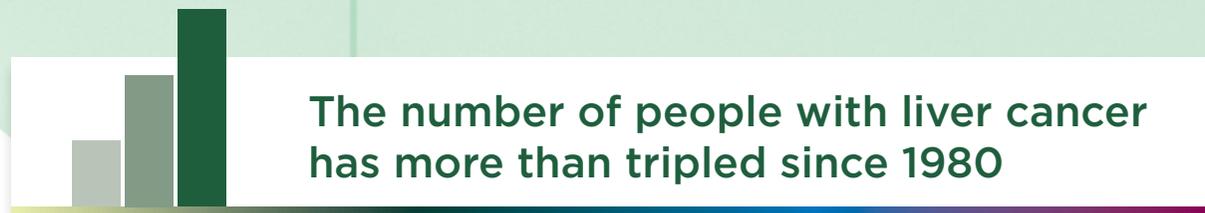


UNDERSTANDING LIVER CANCER

UNDERSTANDING HCC

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

LIVER CANCER IS MORE COMMON THAN YOU THINK...



Hepatocellular carcinoma, also known as HCC, is the most common form of liver cancer in adults. Treatment for HCC may be difficult for several reasons.

- HCC is a type of cancer that often presents in advanced stages. Frequently, patients with HCC also have some other form of chronic liver disease
- In most cases HCC is diagnosed at an advanced stage, meaning that tumor cells cannot be removed or partially removed with surgery

WHAT IS LENVIMA® AND HOW IS IT THOUGHT TO WORK?

LENVIMA is a prescription medicine that is used by itself to treat people with HCC who are not able to have surgery (commonly called unresectable HCC).

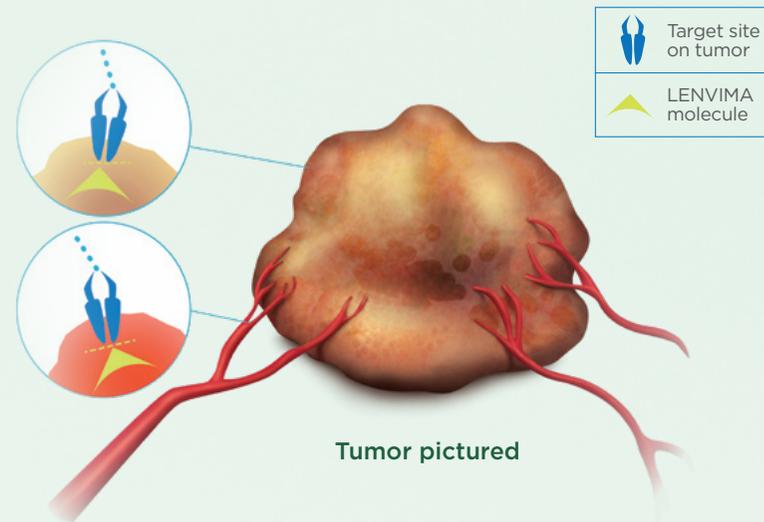
HOW LENVIMA IS THOUGHT TO WORK

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.

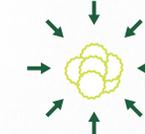
HOW CAN LENVIMA HELP PATIENTS WITH HCC?

LENVIMA was studied in a clinical trial of 954 previously untreated patients with HCC who were not able to have surgery.

In this trial, patients were randomly assigned to receive either LENVIMA or sorafenib. The results showed that treatment with LENVIMA was noninferior (not unacceptably worse) in comparison to sorafenib. Patients treated with LENVIMA **lived for a median of 13.6 months** and patients treated with sorafenib lived for a median of 12.3 months.



Patients treated with LENVIMA (478 patients) lived without their tumor getting worse twice as long as those treated with sorafenib (476 patients), with some living longer and some not as long—median 7.3 months compared with median 3.6 months. A median is the middle number in a list of numbers arranged from lowest to highest.



Almost 3.5 times as many patients treated with LENVIMA (41%) had their tumors shrink compared with patients treated with sorafenib (12%). Ten patients in the LENVIMA arm (2.1%) vs. four patients in the sorafenib arm (0.8%) showed no signs of disease and 184 patients in the LENVIMA arm (38.5%) vs. 55 patients in the sorafenib arm (11.6%) showed some signs of disease.



This trial proved that treatment with LENVIMA may benefit some patients with HCC who cannot be treated with surgery

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



WHAT SHOULD I TELL MY HEALTH CARE TEAM BEFORE TAKING LENVIMA®?

Before you take LENVIMA, tell your health care 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 kidney or liver 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 health care 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 at least 30 days 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, and for at least 1 week after the last dose



Tell your health care 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 health care provider and pharmacist when you get a new medicine.

HOW SHOULD I STORE LENVIMA?



77°F
68°F

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.

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

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 health care provider or pharmacist for information about LENVIMA that is written for health care professionals.



HOW SHOULD I TAKE LENVIMA®?

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

LENVIMA should be taken once a day at the same time

- For example, if you take it at 1:00 PM on Monday, take it on Tuesday at 1:00 PM and so on



About your daily dose of LENVIMA

- Your daily dose of LENVIMA is based on your body weight. Your starting dose may be either two or three 4-mg capsules
- 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

If you miss a dose of LENVIMA

- If you miss a dose of LENVIMA and it is within 12 hours of your missed dose, take it as soon as you remember
- If it is more than 12 hours after your missed dose, skip the missed dose and take the next dose at your regular time

WHAT DO LENVIMA CAPSULES LOOK LIKE?



Capsule not actual size.

For unresectable HCC, LENVIMA is supplied in 4-mg capsules

IF YOU CANNOT SWALLOW LENVIMA CAPSULES WHOLE:



STEP 1.

Use a medicine cup to measure about one tablespoon of water or apple juice and place into a small glass



STEP 2.

Place the LENVIMA capsules into the small glass without breaking or crushing them
(Your starting dose may be 2 or 3 capsules depending on your weight)



STEP 3.

Leave the capsules in the liquid for at least 10 minutes



STEP 4.

Stir the contents of the glass for at least 3 minutes. Drink the mixture



STEP 5.

Rinse the glass with a small amount of additional water or apple juice and swallow the liquid

If you think you have taken more LENVIMA capsules than you should have, please

- call your health care provider
- OR
- go to the nearest hospital emergency room right away



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 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 or visit www.fda.gov/medwatch.



Talk to your doctor about any side effects you may experience

FINANCIAL ASSISTANCE

LEARN ABOUT \$0 CO-PAY

With the LENVIMA \$0 Co-Pay Program, eligible commercially insured patients will pay as little as \$0 out-of-pocket for each prescription. Eisai will pay up to a maximum of \$40,000 per year to assist with the out-of-pocket costs for LENVIMA.*

***Maximum benefit and eligibility:** Depending on the insurance plan, patients could have additional financial responsibility for any amounts over Eisai's maximum liability. **Not available to patients enrolled in state or federal health care programs, including Medicare, Medicaid, Medigap, VA, DoD, or TRICARE.** Offer only available to patients with private, commercial insurance. See www.LENVIMAREIMBURSEMENT.com for complete terms and conditions.

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

For assistance with the LENVIMA \$0 Co-Pay Program, call 1-855-347-2448.

THE 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

FILLING YOUR LENVIMA PRESCRIPTION THROUGH A SPECIALTY PHARMACY

LENVIMA is an oral medication that is available through a Specialty Pharmacy.

LENVIMA is available through 6 Specialty Pharmacies, Accredo®, Biologics, CVS, Onco360, Optum®, and US Bioservices, or through select clinics and hospital pharmacies. Your health care team will tell you which Specialty Pharmacy will supply your medicine. It is important to know the name of your Specialty Pharmacy and to respond promptly to their phone calls and communications.



WWW.ACCREDO.COM
PHONE: 1-844-693-0156
FAX: 1-877-247-4847



WWW.BIOLOGICSINC.COM
PHONE: 1-800-850-4306
FAX: 1-800-823-4506



WWW.CVSSPECIALTY.COM
PHONE: 1-800-799-0692
FAX: 1-855-296-0210



WWW.ONCO360.COM
PHONE: 1-877-662-6633
FAX: 1-877-662-6355



WWW.OPTUM.COM
PHONE: 1-877-719-6349
FAX: 1-877-719-6362



WWW.USBIOSERVICES.COM
PHONE: 1-877-757-0667
FAX: 1-888-899-0067



Check off which Specialty Pharmacy you use and keep this brochure handy as a helpful reminder

PATIENT SUPPORT PROGRAM



The Patient Support Program for LENVIMA® provides a number of services to help you throughout your treatment journey. If you will be receiving LENVIMA from Accredo®, Biologics, CVS, Onco360, Optum®, or US Bioservices, you will be automatically enrolled in these services upon consent, whereas if you will be receiving LENVIMA from another source, you may be enrolled via the LENVIMA Eisai Assistance Program Enrollment Form or by calling the Eisai Assistance Program at 1-866-61-EISAI (1-866-613-4724).



The Patient Support Program includes:

- a **benefits investigation*** to help you understand your coverage for LENVIMA
- a **starter kit** for you that includes key LENVIMA educational materials and helpful resources
- **patient assistance program** provides LENVIMA at no cost to eligible patients with financial need



*Reimbursement assistance for patients receiving LENVIMA from a source other than Accredo®, Biologics, CVS, Onco360, Optum®, or US Bioservices will be provided by the Eisai Assistance Program. Please call 1-866-61-EISAI (1-866-613-4724) for more information.



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.

CONTACT INFORMATION AND QUESTIONS TO ASK YOUR HEALTH CARE TEAM

Keep track of helpful information below.



MY DOCTOR'S
NAME AND PHONE NUMBER:

.....
.....



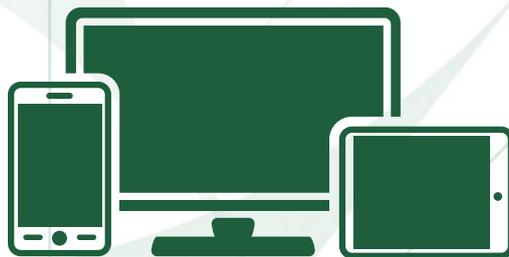
MY NURSE'S
NAME AND PHONE NUMBER:

.....
.....

It is important to ask your health care team any questions you have about LENVIMA. The following are some questions to get you started:

- Why is LENVIMA the right treatment for my liver cancer?
- How long do I need to take LENVIMA?
- What side effects should I expect from taking LENVIMA?
- When should I talk to you about side effects I may experience?
- How can I tell the difference between side effects of the treatment with LENVIMA and symptoms of the cancer?
- How can I tell if LENVIMA is working?
- How often should I check in to see if LENVIMA is working?





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 12-15 and full [Prescribing Information](#).



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