

YOUR GUIDE TO TAKING

LENVIMA[®] for differentiated thyroid cancer (DTC)

LENVIMA is a prescription medicine that is used by itself to treat radioactive iodine-refractory DTC (RAI-R DTC), a type of thyroid cancer that can no longer be treated with radioactive iodine and is progressing.

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



Actor portrayal

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 [click here](#) to view full Prescribing Information.



Actor portrayal

You're not in this by yourself

We're here to support you along the way

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 thyroid cancer that is progressing and can no longer be treated with radioactive iodine (RAI), your doctor believes that at this stage of treatment, LENVIMA[®] may be right for you.

This guide is made to help you

- better understand this type of progressing thyroid cancer
- get started on treatment with LENVIMA
- better understand what you may expect from your treatment with LENVIMA
- learn about support that may be available to you

This guide is intended for people who have been prescribed LENVIMA for differentiated thyroid cancer that is progressing and can no longer be treated with RAI. It may help you better 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 healthcare team.

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Understanding thyroid cancer

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

MORE THAN
43,000
people in the United States will be **diagnosed with thyroid cancer***

*Based on data for 2023.

ABOUT
31,180
women

ABOUT
12,540
men

Thyroid cancer is one of the most common forms of cancer, with over 900,000 currently reported cases in the US. While most cases are detected in the early stages, there is evidence to suggest that the incidence of advanced thyroid cancer has increased in recent years.

Approximately 1.2% of people in the United States will be **diagnosed with thyroid cancer** at some point during their lifetime.†

†Based on 2017-2019 data.

Understanding DTC

Differentiated thyroid cancer, or DTC, includes papillary and follicular (including Hürthle cell) carcinoma.

- DTC 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
- If your cancer is no longer responding to treatment with RAI, that is known as being **radioactive iodine refractory, or RAI-R**

Progression is when your cancer gets worse or spreads over time.

- Sometimes progression may make your symptoms feel worse
- Other times you may not feel new or worsening symptoms at first

Studies have shown:

ABOUT
10%

of people with DTC have more advanced disease

ABOUT
2/3

of those with more advanced disease will be defined as refractory to RAI treatment

TIPS!

It's important to **check in with your doctor regularly** so they can assess if your cancer is progressing.

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

Getting a diagnosis of differentiated thyroid cancer (DTC) that can no longer be treated with radioactive iodine (RAI) and is progressing can be a surprise. If you've been diagnosed with DTC and are no longer able to receive treatment with RAI, LENVIMA is an FDA-approved prescription treatment that may have been prescribed by your healthcare provider.



LENVIMA isn't chemotherapy. It's an oral medicine taken at home 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 the way cancer cells attempt to survive 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

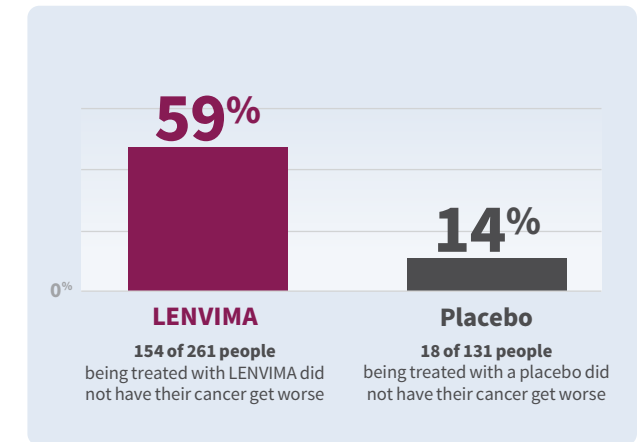
How can LENVIMA help people with RAI-R DTC?

LENVIMA was studied in a clinical trial of 392 people with DTC that was progressing and could no longer be treated with RAI.

In this trial, people with RAI-R DTC were randomly assigned to receive either LENVIMA or placebo, a pill that does not have a medical effect on the body.

A clinical study of LENVIMA showed:

LENVIMA was proven effective in helping people with RAI-R DTC to continue living without their cancer getting worse, with 59% (154 out of 261 people) of people taking LENVIMA staying alive without their cancer getting worse compared to 14% (18 out of 131 people) on placebo at the time of follow-up.



Approx.
5x

Approximately 5x longer survival time for people on LENVIMA without their cancer getting worse (a median of 18.3 months) compared to people treated with placebo (a median of 3.6 months).*

*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
- 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

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

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:

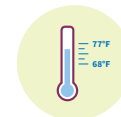
- Your healthcare provider should do a pregnancy test before you start treatment with LENVIMA
- You should use an effective method of birth control during treatment with LENVIMA and for 30 days after the last dose of LENVIMA. Talk with your healthcare provider about birth control methods you can use 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 store LENVIMA?



Store LENVIMA in a room with a steady 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

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.

Actor portrayal

How should I take LENVIMA®?

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

Take LENVIMA exactly how your healthcare provider tells you to take it. Your healthcare provider may adjust your dose during treatment, stop treatment for some time, or completely stop treatment with LENVIMA if you have side effects.

TIPS!

Set a reminder to take the same amount of LENVIMA your doctor prescribes once a day at the same time.

For example, you may want to take your LENVIMA capsules every morning as soon as you wake up or each evening before you go to sleep. The important thing is that you take it at the same time each day, every day, until your doctor decides to make a change.

There are 3 ways to take LENVIMA



Swallow
capsules whole

OR



Mix
with water
or apple juice

OR



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 do I open my LENVIMA blister card?



LENVIMA capsules come in color-coded blister cards that contain medicine for 5 days. The number of capsules you need to take may vary. Depending on your prescription, you may need to take 1 to 3 capsules at the same time each day.

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

TIPS!

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) or 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

TIPS!

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.



Actor portrayal

Understanding and managing side effects

Because of how LENVIMA® is believed to work, it can affect normal, healthy cells in addition to cancer cells. This may lead to serious side effects.

There are steps that can be taken to help manage side effects when taking LENVIMA. Be sure to let your doctor know if you experience any changes in your body, whether you think they may be related to your treatment or not. **Your doctor can work with you to help manage side effects, which may require reducing, temporarily stopping, or permanently discontinuing your treatment with LENVIMA. In the clinical study, most people taking LENVIMA required some dose reduction, interruption, or discontinuation.**

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

Selected Safety Information

- **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.

Selected Safety Information

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

- **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.** 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.

Selected Safety Information

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
- hoarseness

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

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.

TIPS!

Talk to your doctor about any side effects you may experience. For tips on managing certain side effects, visit www.lenvima.com/treatment-tips.

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.

Filling your LENVIMA prescription

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.

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.

TIPS!

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.



Actor portrayal



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's medical record.

Symptom Tracker

You can print out these pages to track any symptoms you may be experiencing. 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		
	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 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 [click here](#) to view full Prescribing Information.



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