

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. WHY AM I USING LENVIMA?

LENVIMA contains the active ingredient Lenvatinib (as lenvatinib mesilate). LENVIMA is used to treat patients with thyroid cancer, advanced kidney cancer (advanced renal cell carcinoma), liver cancer or endometrial cancer.

For more information, see Section [1. Why am I using LENVIMA?](#) in the full CMI.

### 2. WHAT SHOULD I KNOW BEFORE I USE LENVIMA?

Do not use if you have ever had an allergic reaction to LENVIMA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use LENVIMA?](#) in the full CMI.

### 3. WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with LENVIMA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. HOW DO I USE LENVIMA?

- The recommended dose of LENVIMA changes depending on which cancer LENVIMA is being used to treat. Your doctor will tell you the correct dose

More instructions can be found in Section [4. How do I use LENVIMA?](#) in the full CMI.

### 5. WHAT SHOULD I KNOW WHILE USING LENVIMA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking LENVIMA.</li><li>• Keep all of your doctor's appointments so that your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or change the dose without checking with your doctor.</li><li>• Do not take LENVIMA to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operating machinery until you know how LENVIMA affects you</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Avoid alcohol while taking LENVIMA as it may make these effects worse.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine out of the reach of children.</li><li>• Keep your medicine in the original container in a cool dry place where the temperature stays below 30°C.</li></ul>

For more information, see Section [5. What should I know while using LENVIMA?](#) in the full CMI.

### 6. ARE THERE ANY SIDE EFFECTS?

Tell your doctor straight away if you notice any of the following side effects; you may need urgent medical attention:

- Are feeling numb or weak on one side of your body, severe headache, seizure or fit, confusion, difficulty talking, vision changes or feeling dizzy
- Have chest pain or pressure, pain in your arms, back, neck, jaw, being short of breath, rapid or irregular heart rate, coughing, bluish colour to the lips or fingers, feeling very tired
- Have severe pain in your belly (abdomen)
- Have black, tarry, or bloody stools, or coughing up of blood
- Have yellow skin or yellowing of the whites of the eyes (jaundice) or drowsiness, confusion, poor concentration
- Have diarrhoea, feeling and being sick
- Have pain in the mouth, teeth and/or jaw
- Have nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# LENVIMA<sup>®</sup>

**Active ingredient(s):** *lenvatinib (as lenvatinib mesilate)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using LENVIMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LENVIMA.**

**Where to find information in this leaflet:**

- [1. Why am I using LENVIMA?](#)
- [2. What should I know before I use LENVIMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LENVIMA?](#)
- [5. What should I know while using LENVIMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using LENVIMA?

LENVIMA contains the active ingredient Lenvatinib (as Lenvatinib mesilate). LENVIMA is a tyrosine kinase Inhibitor (TKI).

LENVIMA blocks the action of proteins called receptor tyrosine kinases (RTKs), which are involved in the development of new blood vessels that supply oxygen and nutrients to cells and help them to grow. These proteins can be present in high amounts in cancer cells, and by blocking their action LENVIMA may slow the rate at which the cancer cells multiply and the tumour grows and by helping to cut off the blood supply that the cancer needs.

**LENVIMA is used to treat thyroid cancer in adults when radioactive iodine treatment has not helped to stop your disease.**

**It is also used in combination to treat patients with advanced kidney cancer (advanced renal cell carcinoma):**

- **LENVIMA may be used with the medicine pembrolizumab as your first treatment when your kidney cancer has spread or cannot be removed by surgery.**
- **LENVIMA may be used with the medicine everolimus after one course of treatment with another anti-cancer medicine.**

**It is also used to treat liver cancer (hepatocellular carcinoma).**

**It is also used (along with another medicine called pembrolizumab) to treat a kind of uterine cancer called endometrial carcinoma, if laboratory tests show the cancer is not microsatellite instability-high (MSI-H) or**

**mismatch repair deficient (dMMR) and other treatments have not helped stop the disease.**

## 2. What should I know before I use LENVIMA?

Before taking LENVIMA, your doctor may carry out some blood tests, for example to check your blood pressure and your liver or kidney function and to see if you have low levels of salt and high levels of thyroid stimulating hormone in your blood. Your doctor will discuss the results of these tests with you and decide whether you can be given LENVIMA. You may need to have additional treatment with other medicines, to take a lower dose of LENVIMA, or to take extra care due to an increased risk of side effects.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

### Warnings

**Do not use LENVIMA if:**

- you are allergic to Lenvatinib (as Lenvatinib mesilate), or any of the ingredients listed at the end of this leaflet.
- you are breast-feeding .
- Always check the ingredients to make sure you can use this medicine.

**Some of the symptoms of an allergic reaction may include:**

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Check with your doctor if you:**

- Have high blood pressure
- are a woman able to become pregnant
- Have a history of heart problems or stroke
- Are over 75 years of age
- Have had recent surgery or radiotherapy
- Have liver or kidney problems
- have had recent surgery or radiotherapy
- take any medicines for any other condition
- need to have a surgical procedure. Your doctor may consider stopping LENVIMA if you will be undergoing a major surgical procedure as LENVIMA may affect wound healing. LENVIMA may be restarted once adequate wound healing is established.

- have or have had pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. You may be advised to have a dental check-up before starting LENVIMA as bone damage in the jaw (osteonecrosis) has been reported in patients treated with LENVIMA. If you need to undergo an invasive dental treatment or dental surgery, tell your dentist that you are being treated with LENVIMA, particularly when you are also receiving or have received injections of bisphosphonates (used to treat or prevent bone disorders).
- are receiving or have received some medicines used to treat osteoporosis (antiresorptive medicines) or cancer medicines which alter formation of blood vessels (so called angiogenesis inhibitors), as the risk of bone damage in the jaw may be increased.
- belong to an ethnic group other than white or Asian
- weigh less than 60 kg
- have a history of abnormal passageways (known as a fistula) between different organs in the body or from an organ to the skin
- If you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.

#### Conditions you need to look out for

During treatment of your cancer, the breakdown of tumour cells may leak substances into the blood which may lead to a group of complications called tumour lysis syndrome (TLS). This may lead to changes in your kidneys and can be life-threatening. Your doctor will observe and may give you a treatment to reduce the risk. Tell your doctor immediately if you experience signs of TLS (see [6. Are there any side effects?](#)).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

LENVIMA is not recommended in pregnancy.

**You must use a highly effective method of contraception to avoid becoming pregnant while you are taking LENVIMA. You should continue doing this for one month after stopping treatment.**

**Do not breast-feed if you are taking LENVIMA. This is because the medicine may pass into breast milk and may seriously harm your breastfed baby.**

#### Children and Teenagers

**Do not give this medicine to anyone under the age of 18 years.** LENVIMA is not recommended for use in children

and teenagers. The effects of LENVIMA in people younger than 18 years old are not known.

Safety and effectiveness in children younger than 18 years have not been established.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with LENVIMA and affect how it works.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LENVIMA.**

### 4. How do I use LENVIMA?

#### How much to take / use

##### Thyroid Cancer

- If you have thyroid cancer, the recommended dose for this medicine is 24 mg once a day (taken as 2 x 10 mg capsules and 1 x 4 mg capsule).
- If you have severe liver or kidney problems your doctor may prescribe a lower dose of 14 mg once a day (taken as 1 x 10 mg capsule and 1 x 4 mg capsule).

##### Kidney Cancer

- If you have advanced kidney cancer and you have been prescribed Lenvima in combination with pembrolizumab, the recommended daily dose for Lenvima is 20 mg once a day (two 10-mg capsules) in combination with pembrolizumab. Your doctor will also give you an intravenous infusion of pembrolizumab for about 30 minutes every three weeks or every six weeks depending on the dose you are given.
- If you have advanced kidney cancer and you have been prescribed Lenvima in combination with everolimus, the recommended dose for Lenvima is 18 mg once a day (taken as 1 x 10 mg capsule and 2 x 4 mg capsules) in combination with one 5 mg tablet of everolimus once a day.
- If you have severe liver or kidney problems your doctor may prescribe a lower dose of 10 mg once a day (taken as 1 x 10 mg capsule). Your doctor will check to see how much pembrolizumab or everolimus you should receive.

##### Liver Cancer

- If you have liver cancer, the recommended dose for this medicine is usually 12 mg if your body weight is equal to or more than 60 kg (3 capsules of 4 mg) and 8 mg if your body weight is less than 60 kg (2 capsules of 4 mg) once a day.
- Endometrial carcinoma if you have endometrial carcinoma, the recommended dose for this medicine is 20 mg once a day (taken as 2 x 10 mg capsules).

Your doctor will also give you an intravenous infusion of pembrolizumab for about 30 minutes every three weeks or every six weeks depending on the dose you are given.

- If you have severe liver or kidney problems your doctor may prescribe a lower dose of 10 mg once a day (taken as 1 x 10 mg capsule). Your doctor will check to see how much pembrolizumab you should receive.

Your doctor may have prescribed a different dose.

Your doctor may decrease your dose if you have problems with side effects.

Follow the instructions provided and use LENVIMA until your doctor tells you to stop.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.** They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, LENVIMA may not work as well and your problem may not improve.

## When to take LENVIMA

- LENVIMA should be taken at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

## How to take LENVIMA

Caregivers should not open the capsule, in order to avoid repeated exposure to the contents of the capsule.

Swallow the capsules whole with a full glass of water. If unable to swallow the capsule whole, a liquid mixture can be prepared using water, apple juice, or milk.. The liquid mixture may be given by mouth or through a feeding tube. If given through a feeding tube, then the liquid mixture should be prepared using water. If not used at the time of preparation, the liquid mixture may be stored in a covered container and must be refrigerated at 2°C to 8°C for a maximum of 24 hours. Shake the liquid mixture for 30 seconds after removing from the refrigerator. If the liquid mixture is not used within 24 hours of preparation, it should be thrown away.

Preparation and administration of the liquid mixture:

- Place the whole capsule(s) corresponding to the prescribed dose (up to 5 capsules) in a small container (approximately 20 mL (4 tsp) capacity) or oral syringe (20 mL); do not break or crush capsules.
- Add 3 mL of liquid to the container or oral syringe. Wait 10 minutes for the capsule shell (outer surface) to dissolve, then stir or shake the mixture for 3 minutes until the capsules are fully dissolved.
- If liquid mixture is prepared in an oral syringe, cap the syringe, remove plunger and use a second syringe or medicine dropper to add the liquid to the first syringe, then replace plunger prior to mixing.

- Drink the liquid mixture from the container or use an oral syringe to take directly into the mouth or through a feeding tube.
- Next, add an additional 2 mL of liquid to the container, or oral syringe using a second syringe or dropper, swirl or shake and take the liquid mixture. Repeat this step at least twice and until there is no visible sign of the mixture to make sure all of the medication is taken.
- For feeding tubes larger than > 5 French diameter (PVC and PUR tubing) or > 6 French diameter (silicone tubing), at least three rinses of 2 mL water or at least one 4 mL flush is needed to ensure all of the medication is taken.

**Do not mix more than one medicine in the glass at the same time.**

The person preparing the suspension should thoroughly wash their hands before and after the suspension is prepared and the dose taken.

You can take LENVIMA with or without food.

Do not chew, crush or split the capsules. To ensure you get the entire dose, the capsules should be swallowed whole without chewing or crushing.

## If you forget to use LENVIMA

LENVIMA should be used regularly at the same time each day.

**If it is 12 hours or more until your next dose, take the missed dose as soon as you remember. Then take the next dose at the normal time. If it is less than 12 hours until your next dose, skip the missed dose. Then take your next dose at the normal time.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

## If you use too much LENVIMA

If you think that you have used too much LENVIMA, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using LENVIMA?

### Things you should do

#### Call your doctor straight away if you:

- If you do not feel well while you are taking LENVIMA.
- If you become pregnant while taking LENVIMA. Do not stop treatment without first discussing it with your doctor.

Remind any doctor, dentist or pharmacist you visit that you are using LENVIMA.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking LENVIMA. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking LENVIMA. It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

### Things you should not do

- Do not stop using this medicine suddenly.
- Do not take LENVIMA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Patients starting LENVIMA should be carefully observed especially when starting treatment and if the dose is increased.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how LENVIMA affects you.**

LENVIMA may cause side effects that can affect your ability to drive or use machines.

LENVIMA may make you feel dizzy or sleepy, particularly at the beginning of treatment. If this happens to you, do not drive or use any tools or machines.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Avoid alcohol while taking LENVIMA as it may make these effects worse.

### Looking after your medicine

- Keep your medicine in the original container.
- If you take it out of its original container it may not keep well
- Keep your medicine in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If the medicine has expired or the packing is damaged, return it to your pharmacist for disposal.**

### When to discard your medicine

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Your doctor may do blood tests to check for side effects.

Other side effects not listed here may occur in some people.

### Less serious side effects

The following side effects have been reported in clinical trials:

Less serious side effects	What to do
<p><b>Hormone related:</b></p> <ul style="list-style-type: none"><li>• underactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin)</li></ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"><li>• feeling sick and being sick, constipation, diarrhoea, stomach pain, indigestion</li><li>• dry, sore or inflamed mouth, odd taste sensation</li><li>• feeling bloated or gas in the bowel</li><li>• inflammation of the pancreas</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<p>causing severe pain in the upper left part of the belly (abdomen) which may be associated with fever, chills, nausea and vomiting</p> <ul style="list-style-type: none"> <li>anal fistula (a small channel that forms between the anus and surrounding skin)</li> </ul> <p><b>General disorders:</b></p> <ul style="list-style-type: none"> <li>feeling very tired or weak</li> <li>swelling of the legs</li> <li>feeling unwell</li> </ul> <p><b>Muscle or bone related:</b></p> <ul style="list-style-type: none"> <li>swelling and inflammation of the joints, and stiff muscles, bones and joints</li> <li>pain – muscle, joint, back</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>feeling dizzy</li> <li>headache</li> </ul> <p><b>Blood test related:</b></p> <ul style="list-style-type: none"> <li>changes in blood test results for magnesium (low), potassium levels (low and high), calcium levels (low), cholesterol (high) and thyroid stimulating hormone (high), high lipase and amylase levels (enzymes involved in digestion), high creatinine levels (blood test results for kidney function). decreases in the number of white blood cells</li> <li>changes in blood test results for liver function</li> <li>changes in blood test results for kidney function (high blood urea levels)</li> </ul> <p><b>Metabolism related:</b></p> <ul style="list-style-type: none"> <li>loss of appetite or weight loss</li> <li>loss of body fluids (dehydration)</li> </ul> <p><b>Psychiatric related:</b></p> <ul style="list-style-type: none"> <li>trouble sleeping</li> <li>feeling sleepy (drowsiness or somnolence)</li> </ul> <p><b>Liver or gallbladder related:</b></p> <ul style="list-style-type: none"> <li>liver damage</li> <li>inflammation of the gallbladder</li> </ul>		<p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>urinary infections (increased frequency in urination and difficult or painful passing of urine)</li> <li>painful infection or irritation near the anus</li> </ul> <p><b>Kidney or bladder related:</b></p> <ul style="list-style-type: none"> <li>reduced kidney function or failure</li> <li>increased protein in the urine</li> </ul> <p><b>Breathing or respiratory system related:</b></p> <ul style="list-style-type: none"> <li>cough or hoarse voice</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>rash</li> <li>redness, soreness and swelling of the skin on the hands and feet (hand-foot syndrome)</li> <li>dry skin, thickening and itching of skin</li> <li>hair loss</li> <li>wound healing problems</li> </ul> <p><b>Heart or circulatory system related:</b></p> <ul style="list-style-type: none"> <li>high or low blood pressure</li> <li>heart palpitations</li> <li>bleeding (most commonly nose bleeds, but may include bleeding from other sites such as blood in the urine, bruising, bleeding from the gums or gut wall)</li> <li>bruising – signs of low level of platelets in the blood</li> <li>Bulging and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)</li> </ul>	
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### Serious side effects

When you take LENVIMA, you may have some serious side effects. These side effects can sometimes become life-threatening and can lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

If you have any of the following symptoms, call or see your doctor right away.

Serious side effects	What to do
<p><b>Signs and symptoms of a stroke or mini-stroke, bleeding on your brain or the effect on your brain of a severe increase in blood pressure:</b></p> <ul style="list-style-type: none"> <li>feeling numb or weak on one side of your body,</li> <li>severe headache</li> <li>seizure or fit</li> <li>confusion</li> <li>difficulty talking</li> <li>vision changes</li> <li>feeling dizzy</li> </ul> <p><b>Signs and symptoms of a heart problem or a blood clot in your lungs or a leak of air from your lung into your chest so your lung cannot inflate:</b></p> <ul style="list-style-type: none"> <li>chest pain or pressure, pain in your arms, back, neck, jaw</li> <li>being short of breath</li> <li>rapid or irregular heart rate</li> <li>coughing</li> <li>bluish colour to the lips or fingers</li> <li>feeling very tired</li> </ul> <p><b>Signs and symptoms of a hole in the wall of your gut or a fistula (a hole your gut which links through a tube-like passage to another part of your body or skin):</b></p> <ul style="list-style-type: none"> <li>have severe pain in your belly (abdomen)</li> <li>other types of fistulae (an abnormal connection between different organs in the body or from the skin to an underlying structure such as throat and windpipe). Symptoms would depend on where the fistula is located. Talk to your doctor if you experience any new or unusual symptoms such as coughing when swallowing</li> </ul> <p><b>Signs and symptoms of bleeding inside your body:</b></p> <ul style="list-style-type: none"> <li>have black, tarry, or bloody stools</li> <li>coughing up of blood</li> <li>severe pain in the back, chest or abdomen associated with tearing in the wall of the aorta and internal bleeding</li> </ul> <p><b>Signs and symptoms of liver problems including liver failure:</b></p> <ul style="list-style-type: none"> <li>yellow skin or yellowing of the</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<ul style="list-style-type: none"> <li>whites of the eyes (jaundice)</li> <li>drowsiness, confusion, poor concentration, loss of consciousness</li> </ul> <p><b>Signs and symptoms of bone damage in the jaw (osteonecrosis):</b></p> <ul style="list-style-type: none"> <li>pain in the mouth, teeth and/or jaw</li> <li>swelling or sores inside the mouth</li> <li>numbness or a feeling of heaviness in the jaw loosening of a tooth</li> </ul> <p><b>Signs and symptoms of complications due to the breakdown products of dying cancer cells and known as tumour lysis syndrome (TLS):</b></p> <ul style="list-style-type: none"> <li>nausea</li> <li>shortness of breath</li> <li>irregular heartbeat</li> <li>muscular cramps</li> <li>seizure</li> <li>clouding of urine</li> <li>tiredness</li> </ul> <p><b>Very common side effects that can become serious if they cause you to become dehydrated, which can lead to kidney failure. Your doctor can give you medicine to reduce these side effects:</b></p> <ul style="list-style-type: none"> <li>diarrhoea</li> <li>feeling and being sick</li> </ul>	
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## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What LENVIMA contains

<b>Active ingredient (main ingredient)</b>	lenvatinib (as lenvatinib mesilate)
<b>Other ingredients (inactive ingredients)</b>	Calcium carbonate Mannitol

	Cellulose – microcrystalline Hydroxypropylcellulose, Low-substituted hydroxypropylcellulose Talc – purified Hypromellose Titanium dioxide Iron oxide yellow Iron oxide red Shellac Iron oxide black Potassium hydroxide Propylene glycol
<b>Potential allergens</b>	none

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What LENVIMA looks like**

4 mg hard capsule: A yellowish-red body and yellowish-red cap, approximately 14.3 mm in length, marked in black ink with “E” on the cap, and “LENV 4 mg” on the body.

10 mg hard capsule: A yellow body and yellowish-red cap, approximately 14.3 mm in length, marked in black ink with “E” on the cap, and “LENV 10 mg” on the body.

#### **Australian Register Numbers:**

AUST R 233425: LENVIMA lenvatinib 4mg hard capsule blister pack

AUST R 233426: LENVIMA lenvatinib 10mg hard capsule blister pack

### **Who distributes LENVIMA**

Eisai Australia Pty Ltd

Level 6, 60 City Road,

Southbank, VIC, 3006

[medinfo\\_australia@eisai.net](mailto:medinfo_australia@eisai.net)

This leaflet was prepared in April 2025.