# Lenvima®

## Lenvatinib (as lenvatinib mesilate) hard capsules

*(len-va-ti-nib)*

**New Zealand Consumer Medicine Information**

## WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Lenvima.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.**

You may need to read it again.

## WHAT LENVIMA IS USED FOR

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 anticancer 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 other treatments have not helped stop the disease

It contains the active ingredient lenvatinib (as lenvatinib mesilate).

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.

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

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

Lenvima should be used with caution in patients who:
- have high blood pressure
- have a history of heart problems or stroke
- are over 65 years of age
- have had recent surgery or radiotherapy
- have liver or kidney problems.

Lenvima is not recommended for use in children and teenagers. The effects of Lenvima in people younger than 18 years old are not known.

## BEFORE YOU TAKE LENVIMA

### *When you must not take it*

**Do not take this medicine if:**
- you are allergic to lenvatinib (as lenvatinib mesilate), the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- you are breast-feeding

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

**Do not give this medicine to anyone under the age of 18 years.**

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

**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.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### *Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had:**
- high blood pressure
- are a woman able to become pregnant
- a history of heart problems or stroke
- liver problems
- kidney problems
- recent surgery or radiotherapy
- 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.

**Tell your doctor if you:**
- are over 75 years old
- 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 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 SIDE EFFECTS).

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**
Lenvima is not recommended in pregnancy or while breastfeeding.

**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.**

It is not known whether the ingredients of Lenvima can pass into breast milk.

The doctor will weigh up the benefit and/or risks to you and your baby of taking Lenvima while you are breastfeeding.

**If you have not told your doctor about any of the above, tell him/her before you start taking 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.

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy,**

**supermarket or health food shop.**

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking this medicine.

## HOW TO TAKE LENVIMA

**Follow all directions given to you by your doctor or pharmacist carefully.**
They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

### *How much to take*

**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). Your doctor will also give you pembrolizumab either 200 mg every 3 weeks or 400 mg every 6 weeks administered as an intravenous infusion over 30 minutes.
- 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 everlimus you should receive.

**Liver Cancer**
- It 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.

**Uterine Cancer**
- 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 pembrolizumab either 200 mg every 3 weeks or 400 mg every 6 weeks administered as an intravenous infusion over 30 minutes.

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

Your doctor may have prescribed a different dose.

**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.

### *How to take it*

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 2ºC to 8ºC 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.

Caregivers should not open capsules to avoid exposure to the contents of the capsule.

### *When to take Lenvima*

**Take your medicine 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 long to take Lenvima*

**Continue taking your medicine for as long as your doctor tells you.**
Do not stop unless your doctor advises you to.

Your doctor may reduce your dose slowly to avoid side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### *If you forget to take it*

**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 take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Lenvima. Do this even if there are no signs of discomfort or poisoning.**
You may need urgent medical attention.

## WHILE YOU ARE TAKING LENVIMA

### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lenvima.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking 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 become pregnant while taking Lenvima, tell your doctor immediately.** Do not stop

treatment without first discussing it with your doctor.

**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 must not do*

**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.**

### *Things to be careful of*

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

**Do not drive or operating machinery 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.

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

## SIDE EFFECTS

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lenvima**
All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

- feeling numb or weak on one side of your body, severe headache, seizure or fit, confusion, difficulty talking, vision changes or feeling dizzy – these may be signs of a stroke, bleeding on your brain or the effect on your brain of a severe increase in blood pressure;
- 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 – these may be signs of a heart problem or blood clot in your lungs or a leak of air from your lung into your chest so your lung cannot inflate;
- severe pain in your belly (abdomen) – this may be due to 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);
- black, tarry, or bloody stools, or coughing up of blood – these may be signs of bleeding inside your body;
- yellow skin or yellowing of the whites of the eyes (jaundice) or drowsiness, confusion, poor concentration – these may be signs of liver problems.
- diarrhoea, feeling and being sick – these are 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.
- 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 – these could be signs of bone damage in the jaw (osteonecrosis).
- nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness. These symptoms may be complications due to the breakdown products of dying cancer cells and known as tumour lysis syndrome (TLS).

**Other side effects include:**

**Very common** (may affect more than 1 user in 10) are:

- high or low blood pressure
- loss of appetite or weight loss
- feeling sick and being sick, constipation, diarrhoea, stomach pain, indigestion
- feeling sleepy (drowsiness or somnolence).
- feeling very tired or weak
- cough or hoarse voice
- swelling of the legs
- rash
- dry, sore or inflamed mouth, odd taste sensation

- swelling and inflammation of the joints, and stiff muscles, bones and joints
- feeling dizzy
- hair loss
- 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)
- trouble sleeping
- increased protein in the urine
- urinary infections (increased frequency in urination and difficult or painful passing of urine)
- pain – muscle, joint, headache, back
- redness, soreness and swelling of the skin on the hands and feet (hand-foot syndrome)
- underactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin)
- changes in blood test results for potassium levels (low), calcium levels (low), cholesterol (high) and thyroid stimulating hormone (high), high lipase and amylase levels (enzymes involved in digestion), high creatine levels (blood test results for kidney function)
- decreases in the number of white blood cells
- bruising and difficulty in wound healing – signs of low level of platelets in the blood
- changes in blood test results for liver function

**Common** (may affect up to 1 user in 10) are:
- loss of body fluids (dehydration)
- heart palpitations
- dry skin, thickening and itching of skin
- feeling bloated or gas in the bowel
- heart problems or blood clots in the lungs (difficulty breathing, chest pain) or other organs
- live failure
- drowsiness, confusion, poor concentration, loss of consciousness that may be signs of liver failure
- feeling unwell
- stroke
- inflammation of the gallbladder
- inflammation of the pancreas
- anal fistula (a small channel that forms between the anus and surrounding skin)
- changes in blood test results for magnesium (low) and potassium (high)
- changes in blood test results for kidney function (high blood urea levels) and kidney failure

**Uncommon** (may affect up to 1 user in 100) are:
- painful infection or irritation near the anus
- mini-stroke
- liver damage
- severe pain in the upper left part of the belly (abdomen) which may be associated with fever, chills, nausea and vomiting
- wound healing problems
- bone damage in the jaw (osteonecrosis)
- 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

**Rare** (may affect up 1 user in 1,000):
- nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness. These symptoms may be complications due to the breakdown products of dying cancer cells and known as tumour lysis syndrome (TLS)

**Not Known** (the following side effects have been reported since the marketing of Lenvima but the frequency for them to occur is not known)
- severe pain in the back, chest or abdomen associated with tearing in the wall of the aorta and internal bleeding
- shortness of breath or severe chest pain which may be signs of a collapsed lung
- an enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).

If you get any side effects, talk to your doctor or pharmacist.

This includes any side effects not listed in this leaflet.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**
Other side effects not listed above may also occur in some people.

## AFTER TAKING LENVIMA

### *Storage*

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.

Do not store Lenvima or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

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

### *Disposal*

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.

## PRODUCT DESCRIPTION

### *What it 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 "Є" 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 "Є" on the cap, and "LENV 10 mg" on the body.

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

Excipient Ingredients:
- 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

This medicine does not contain gluten, tartrazine or any other azo dyes.

## SPONSOR

Lenvima is supplied in New Zealand by:

Eisai New Zealand Ltd.
Simpson Grierson, Level 27
88 Shortland Street, Auckland
Central Auckland, 1010, NZ

Telephone: 0800 00 52 06

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