PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is to be supplied upon a physician's prescription only

Lenvima® 4 mg Hard Capsules	Lenvima® 10 mg Hard Capsules
Composition: **The active ingredient and its quantity:** Each hard capsule contains: Lenvatinib (as mesilate) 4 mg	**Composition:** **The active ingredient and its quantity:** Each hard capsule contains: Lenvatinib (as mesilate) 10 mg

For list of excipients, please see section 6.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if you think that their illness is similar to yours.

This medicine is not intended for use in children and adolescents under 18 years of age. The effects of LENVIMA in people younger than 18 years old are unknown.

Treatment with LENVIMA should be initiaited and supervised by a physician experienced in the use of anticancer therapies.

1. What is the medicine intended for?

- For the treatment of advanced thyroid cancer in adults when radioactive iodine treatment has not helped to stop the disease.
- In combination with everolimus, for the treatment of advanced clear cell kidney cancer in adults when other treatments [called "targeted therapy VEGF (Vascular endothelial growth factor)"] have not helped stop the disease.
- As monotherapy for the treatment of liver cancer *(hepatocellular carcinoma)* in adults who have not previously been treated with systemic therapy with another anticancer medicine. People get LENVIMA when their liver cancer has spread or cannot be taken out by surgery.
- In combination with pembrolizumab to treat advanced or recurrent cancer of the lining of the uterus (*endometrial carcinoma*) in adults whose cancer has spread while or after being previously treated with another platinum containing anticancer therapy, and which cannot be taken out by surgery or radiation treatment.
- In combination with pembrolizumab as the first treatment for adults with advanced kidney cancer (*advanced renal cell carcinoma*).

LENVIMA blocks the action of proteins called tyrosine kinases receptors, 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 help to cut off the blood supply that the cancer needs.

Therapeutic group:
Tyrosine kinase inhibitors for the treatment of cancer.

2. Before using the medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (lenvatinib) or to any of the other ingredients of this medicine *(see section 6)*.
- You are breast-feeding (see section below "*Pregnancy, Breast-feeding and Contraception*").

Special warnings regarding the use of this medicine
Before beginning treatment with LENVIMA tell your physician if:

- You have high blood pressure
- You are a woman of childbearing age (see section below "*Pregnancy, Breast-feeding and Contraception*")
- You have a history of heart problems or stroke
- You have liver or kidney problems
- You have had recent surgery or radiotherapy
- You need to have a surgical procedure. Your physician 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
- You are over 75 years old
- You belong to an ethnic group other than White or Asian
- You weigh less than 60 kg
- You have a history of abnormal connections (known as a fistula) between different organs in the body or from an organ to the skin
- you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- 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.

Children and adolescents:
LENVIMA is not recommended for use in children and adolescents younger than 18 years old.

Tests and Follow Up:
Before taking LENVIMA, your physician may carry out some 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 physician 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.

If you are not sure talk to your doctor before taking LENVIMA.

The physician will test for:

- High blood pressure - blood pressure should be monitored after one week of treatment, then every two weeks for the first two months of treatment and monthly thereafter
- Early signs of kidney damage
- Early signs of liver damage – liver function tests should be monitored before initiation of treatment, then every two weeks for the first two months of treatment and monthly thereafter
- Heart problems - the physician will perform regular ECG testing according to his discretion
- Low blood salt level - before starting treatment, electrolyte disturbances should be corrected, if any exist. In addition, the physician will peform regular periodic tests of electrolytes (magnesium, potassium, calcium) at his discretion. Blood calcium levels should be monitored at least once a month.
- Thyroid function – the physician will perform thyroid function tests before starting treatment and during treatment, at his discretion. High level of thyroid stimulating hormone (TSH) in the blood - if necessary, the physician will adjust your dosage of thyroid hormone.
- Protein in the urine

Tell the physician or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.

Use of this medicine and food:
The capsules may be taken with or without food.

Pregnancy, Breast-feeding and Contraception:
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before taking this medicine.

- If you are of childbearing age and could become pregnant, use highly effective contraception while taking LENVIMA, and for at least one month after you finish treatment. Because it is not known if LENVIMA can reduce the effect of the oral contraceptive pill, if oral contraceptive pill is your normal method of contraception you should ensure you also add a barrier method such as cervical cap or condoms if you have sex during treatment with LENVIMA.
- Do not take LENVIMA if you are planning to become pregnant during your treatment. This is because it may seriously harm the foetus.
- If you become pregnant while being treated with LENVIMA, tell your physician immediately. Your physician will help you decide whether the treatment should be continued.
- Do not breast-feed if you are taking LENVIMA. This is because the medicine passes into breast milk and may seriously harm your breastfed baby.

Driving and using machines:
LENVIMA may cause side effects that can affect your ability to drive or use machines. Avoid driving or using machines if you feel dizzy or tired.

3. How to use this medicine

Always use according to the physician's instructions. Check with the physician or pharmacist if you are not sure.
The dosage and administration will be determined by the physician only.

For treatment of advanced thyroid cancer: The usual recommended dose for adults is:

- 24 mg once a day (2 capsules of 10 mg and one capsule of 4 mg).
- If you have severe liver or kidney problems the recommended dose is 14 mg once a day (one capsule of 10 mg and one capsule of 4 mg).
- Your physician may reduce your dose if you experience side effects.

For treatment of advanced clear cell kidney cancer: The usual recommended dose for adults is:

- 18 mg once a day (one capsule of 10 mg and 2 capsules of 4 mg) in combination with one tablet (5 mg) of everolimus once a day.
- If you have severe liver or kidney problems the recommended dose is 10 mg once a day (one capsule of 10 mg) in combination with one tablet (5 mg) of everolimus once a day.
- Your physician may reduce your dose if you experience side effects.

For treatment of liver cancer: The usual recommended dose for adults is:

- The recommended dose of LENVIMA depends on your body weight when you first start treatment. If you weigh 60 kg or more, the dose is usually 12 mg once a day (3 capsules of 4 mg). If you weigh less than 60 kg, the dose is usually 8 mg once a day (2 capsules of 4 mg).
- Your physician may reduce your dose if you experience side effects.

For treatment of advanced or recurrentendometrial carcinoma: The usual recommended dose for adults is:

- The recommended dose of LENVIMA is 20 mg once a day (2 capsules of 10 mg), in combination with pembrolizumab. The pembrolizumab is given by your doctor as an infusion into your vein, 200 mg every 3 weeks.
- Your doctor may reduce your dose if you have problems with side effects.

For treatment of advanced renal cell carcinoma: The usual recommended dose for adults is:

- The recommended dose of LENVIMA is 20 mg once a day (2 capsules of 10 mg), in combination with pembrolizumab. The pembrolizumab is given by your doctor as an infusion into your vein, 200 mg every 3 weeks.
- Your doctor may reduce your dose if you have problems with side effects.

Do not exceed the recommended dose.
How to take LENVIMA:

- Swallow the capsules whole with water or dissolved. To dissolve them, pour a tablespoon of water or apple juice into a small glass and put the capsules whole into the liquid (without breaking or crushing them). Leave for at least 10 minutes then stir for at least 3 minutes to dissolve the capsule shells. Drink the mixture. After drinking, add to the glass the same amount of water or apple juice, swirl and swallow.
- Take the capsules at about the same time each day.
- Caregivers should avoid exposure to the contents of the capsules. Therefore, the capsules should not be opened.

Treatment duration:
You will usually carry on taking this medicine as long as you are getting benefit.

If you have accidentally taken a higher dosage you may suffer from the following side effects: high blood pressure, nausea, diarrhea, fatigue, inflammation of the mucous membrane of the mouth, high level of protein in the urine, headache, worsening of hand-foot syndrome (redness, pain and swelling of the skin on palms of the hands and soles of the feet), kidney or heart failure.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the set time, you should:

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

- If it is 12 hours or more until the 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 the next dose: skip the missed dose. Then take the next dose at the normal time.

Continue with the treatment as recommended by the physician. Even if there is an improvement in your health condition, do not stop taking this medicine without consulting the physician.

- **Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.**

If you have any further questions regarding the use of this medicine, consult the physician or pharmacist.

4. Side Effects

Like all medicines, LENVIMA may cause side effects in some users. Do not be alarmed while reading the list of side effects; you may not suffer from any of them.

Refer to the physician immediately if you suffer from any of the following side effects – you may need urgent medical treatment:

- feeling numb or weak on one side of your body, severe headache, seizure, confusion, difficulty talking, vision changes or feeling dizzy - these may be signs of a stroke, bleeding in your brain, or the effect on your brain as a result of a severe increase in blood pressure.
- chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, rapid or irregular heart rate, coughing, bluish colour to lips or fingers, feeling very tired – these may be signs of a heart problem, a blood clot in the lung 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 in the 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, nausea and vomiting - these are very common side effects that can become serious if they cause you to become dehydrated, which can lead to kidney failure. Your physician may 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).

  Tell your doctor straight away if you notice any of the side effects above.

Additional side effects:

The following side effects may happen with this medicine when given alone:

Very common side effects: (affect more than 1 in 10 patients)

- low levels of platelets in the blood which may lead to bruising and difficulty in wound healing
- decrease in the number of white blood cells
- underactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin) and changes in blood test results for thyroid stimulating hormone (high)
- changes in blood test results for potassium levels (low) and calcium levels (low)
- changes in blood test results for magnesium (low) and cholesterol (high)
- loss of appetite or weight loss
- trouble sleeping
- feeling dizzy
- headache
- bleeding (most commonly nose bleeds, but also other types of bleeding such as blood in the urine, bruising, bleeding from the gums or gut wall)
- high or low blood pressure
- hoarse voice
- feeling sick (nausea) and being sick (vomiting), constipation, diarrhoea, abdominal pain, indigestion
- dry, sore, or inflamed mouth, odd taste sensation
- increase in lipase and amylase (enzymes involved in digestion)
- changes in blood test results for liver function
- redness, soreness and swelling of the skin on the hands and feet (palmar-plantar erythrodysaesthesia)
- rash
- hair loss
- back pain
- joint or muscle pain
- changes in urine tests for protein (high) and urinary infections (increased frequency in urination and pain in passing urine)
- changes in blood test results for kidney function and kidney failure
- feeling very tired or weak
- swelling of the legs

Common side effects: (affect up to 1 in 10 patients)

- loss of body fluids (dehydration)
- heart palpitations
- dry skin, thickening and itching of the skin
- feeling bloated or having excess wind
- heart problems or blood clots in the lungs (difficulty breathing, chest pain) or other organs which may include chest pain or pressure, pain in your arms, back, neck or jaw, being short of breath, rapid or irregular heart rate, coughing, bluish colour to lips or fingers, and feeling very tired
- liver failure
- drowsiness, confusion, poor concentration, loss of consciousness that may be signs of liver failure
- feeling unwell
- inflammation of the gallbladder
- signs of a stroke, including feeling numb or weak on one side of your body, severe headache, seizure, confusion, difficulty talking, vision changes or feeling dizzy
- anal fistula (a small channel that forms between the anus and the surrounding skin)
- a hole (perforation) in the stomach or intestines

Uncommon side effects: (affect up to 1 in 100 patients)

- painful infection or irritation near the anus
- severe pain in the upper left part of the belly (abdomen) which may be associated with fever, chills, nausea and vomiting (splenic infarction)
- mini-stroke
- severe difficulty breathing and chest pain, caused by a leak of air from your lung into your chest so your lung cannot inflate
- inflammation of the pancreas
- inflammation of the colon (colitis)
- liver damage
- bone damage in the jaw (osteonecrosis)
- wound healing problems
- decreased secretion of hormones produced by adrenal glands

Side effect with unknown frequency: (the following side effects have been reported since the marketing of LENVIMA but the frequency for them to occur is not known)

An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).

- other types of fistulae (an abnormal connection between different organs in the body or between the skin and an underlying structure such as throat and windpipe). Symptoms depend on where the fistula is located. Talk to your physician if you experience any new or unusual symptoms such as coughing when swallowing.

The following side effects may happen with this medicine when given in combination with everolimus

Very common side effects: (affect more than 1 in 10 patients)

- low levels of platelets in the blood which may lead to bruising and difficulty in wound healing
- decrease in the number of white blood cells
- underactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin) and changes in blood test results for thyroid stimulating hormone (high)
- changes in blood test results for potassium levels (low) and calcium levels (low)
- changes in blood test results for magnesium (low) and cholesterol (high)
- loss of appetite or weight loss
- trouble sleeping
- headache
- bleeding (most commonly nose bleeds, but also other types of bleeding such as blood in the urine, bruising, bleeding from the gums or gut wall)
- high blood pressure
- hoarse voice
- feeling sick (nausea) and being sick (vomiting), constipation, diarrhoea, abdominal pain, indigestion
- sore, or inflamed mouth, odd taste sensation
- increase in lipase and amylase (enzymes involved in digestion)
- changes in blood test results for liver function
- redness, soreness and swelling of the skin on the hands and feet (palmar-plantar erythrodysaesthesia)
- rash
- back pain
- joint or muscle pain
- changes in urine tests for protein (high)
- changes in blood test results for kidney function and kidney failure
- feeling very tired or weak
- swelling of the legs

Common side effects: (affect up to 1 in 10 patients)

- urinary infections (increased frequency in urination and pain in passing urine)
- loss of body fluids (dehydration)
- feeling dizzy
- heart palpitations
- feeling bloated or having excess wind
- heart problems or blood clots in the lungs (difficulty breathing, chest pain) or other organs which may include chest pain or pressure, pain in your arms, back, neck or jaw, being short of breath, rapid or irregular heart rate, coughing, bluish colour to lips or fingers, and feeling very tired
- low blood pressure
- severe difficulty breathing and chest pain, caused by a leak of air from your lung into your chest so your lung cannot inflate
- dry mouth
- feeling unwell
- inflammation of the gallbladder
- hair loss

Uncommon side effects: (affect up to 1 in 100 patients)

- painful infection or irritation near the anus
- signs of a stroke, including feeling numb or weak on one side of your body, severe headache, seizure, confusion, difficulty talking, vision changes or feeling dizzy
- mini-stroke (transient ischaemic attack)
- inflammation of the pancreas
- anal fistula (a small channel that forms between the anus and the surrounding skin)
- inflammation of the colon (colitis)
- liver failure or signs of liver damage, including yellow skin or yellowing of the whites of the eyes (jaundice) or drowsiness, confusion, poor concentration
- bone damage in the jaw (osteonecrosis)
- dry skin, thickening and itching of the skin
- wound healing problems
- other types of fistulae (an abnormal connection between different organs in the body or between the skin and an underlying structure such as throat and windpipe). Symptoms depend on where the fistula is located. Talk to your doctor if you experience any new or unusual symptoms such as coughing when swallowing.
- decreased secretion of hormones produced by adrenal glands

Side effect with unknown frequency: (the following side effects have been reported since the marketing of LENVIMA but the frequency for them to occur is not known)

- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).

The following side effects may happen with this medicine when given in combination with pembrolizumab for advanced kidney cancer:

Very common (may affect more than 1 in 10 people)

- low levels of platelets in the blood which may lead to bruising and difficulty in wound healing
- decrease in the number of white blood cellsunderactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin) and changes in blood test results for thyroid stimulating hormone (high)
- changes in blood test results for potassium levels (low) and calcium levels (low)
- changes in blood test results for magnesium (low) and changes in blood test results for cholesterol (high)
- loss of appetite or weight loss
- trouble sleeping
- feeling dizzy
- headache
- bleeding (most commonly nose bleeds, but also other types of bleeding such as blood in the urine, bruising, bleeding from the gums or gut wall)
- high blood pressure
- hoarse voice
- nausea and vomiting, constipation, diarrhoea, abdominal pain, indigestion
- dry, sore, or inflamed mouth, odd taste sensation
- increase in lipase and amylase (enzymes involved in digestion)
- changes in blood test results for liver function redness, soreness and swelling of the skin on the hands and feet (palmar-plantar erythrodysaesthesia)
- rash
- back pain
- joint or muscle pain
- changes in urine tests for protein (high)
- changes in blood test results for kidney function and kidney failure
- feeling very tired or weak
- swelling of the legs

Common (may affect up to 1 in 10 people)

- urinary infections (increased frequency in urination and pain in passing urine)
- loss of body fluids (dehydration)
- heart palpitations
- heart problems or blood clots in the lungs (difficulty breathing, chest pain) or other organs which may include chest pain or pressure, pain in your arms, back, neck or jaw, being short of breath, rapid or irregular heart rate, coughing, bluish colour to lips or fingers, and feeling very tired
- low blood pressure
- inflammation of the pancreas
- inflammation of the colon (colitis)
- feeling bloated or having excess wind
- inflammation of the gallbladder
- dry skin, thickening and itching of the skin
- hair loss
- feeling unwell
- decreased secretion of hormones produced by adrenal glands

Uncommon (may affect up to 1 in 100 people)

- painful infection or irritation near the anus
- signs of a stroke, including feeling numb or weak on one side of your body, severe headache, seizure, confusion, difficulty talking, vision changes or feeling dizzy
- mini-stroke
- severe difficulty breathing and chest pain, caused by a leak of air from your lung into your chest so your lung cannot inflate
- anal fistula (a small channel that forms between the anus and the surrounding skin)
- liver failure or signs of liver damage, including yellow skin or yellowing of the whites of the eyes (jaundice) or drowsiness, confusion, poor concentration
- wound healing problems
- 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.

Not Known (the following side effects have been reported since the marketing of medicine but the frequency for them to occur is not known) an enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).

The following side effects may happen with this medicine when given in combination with pembrolizumab for advanced or recurrent cancer of the lining of the uterus:

Very common (may affect more than 1 in 10 people)

- changes in urine tests for protein (high) and urinary infections (increased frequency in urination and pain in passing urine)
- low levels of platelets in the blood which may lead to bruising and difficulty in wound healing
- decrease in the number of white blood cells
- decrease in the number of red blood cells
- underactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin) and changes in blood test results for thyroid stimulating hormone (high)
- overactive thyroid (symptoms can include rapid heart rate, sweating and weight loss)
- changes in blood test results for potassium levels (low) and calcium levels (low)
- changes in blood test results for magnesium levels (low) and cholesterol levels (high)
- loss of appetite or weight loss
- feeling dizzy
- headache
- back pain
- dry, sore, or inflamed mouth, odd taste sensation
- bleeding (most commonly nose bleeds, but also other types of bleeding such as blood in the urine, bruising, bleeding from the gums or gut wall)
- high blood pressure
- hoarse voice
- nausea and vomiting, constipation, diarrhoea, abdominal pain
- increase in amylase (enzyme involved in digestion)
- increase in lipase (enzyme involved in digestion)
- changes in blood test results for liver function
- changes in blood test results for kidney function
- redness, soreness and swelling of the skin on the hands and feet (palmar-plantar erythrodysaesthesia)
- rash
- joint or muscle pain
- feeling very tired or weak
- swelling of the legs

Common (may affect up to 1 in 10 people)

- loss of body fluids (dehydration)
- trouble sleeping
- heart palpitations
- low blood pressure
- blood clots in the lungs (difficulty breathing, chest pain)
- inflammation of the pancreas
- feeling bloated or having excess wind
- indigestion
- inflammation of the gallbladder
- hair loss
- kidney failure
- feeling unwell
- inflammation of the colon (colitis)
- decreased secretion of hormones produced by adrenal glands
- a hole (perforation) in the stomach or intestines

Uncommon (may affect up to 1 in 100 people)

- headache, feeling confused, seizure, and changes in vision
- signs of a stroke, including feeling numb or weak on one side of your body, severe headache, seizure, confusion, difficulty talking, vision changes or feeling dizzy
- mini-stroke
- signs of a heart problem, including chest pain or pressure, pain in your arms, back, neck or jaw, being short of breath, rapid or irregular heart rate, coughing, bluish colour to lips or fingers, and feeling very tired
- severe difficulty breathing and chest pain, caused by a leak of air from your lung into your chest so your lung cannot inflate
- painful infection or irritation near the anus
- anal fistula (a small channel that forms between the anus and the surrounding skin)
- liver failure or signs of liver damage, including yellow skin or yellowing of the whites of the eyes (jaundice) or drowsiness, confusion, poor concentration
- dry skin, thickening and itching of the skin
- wound healing problems

If any of the side effects appears, if any of the side effects worsen or if you experience any side effect not mentioned in this leaflet, consult the physician or pharmacist.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: https://sideeffects.health.gov.il

Lenvima® 4 mg hard capsules
Lenvima® 10 mg hard capsules
לנווימה 4 מ"ג כמוסות קשיחות
לנווימה 10 מ"ג כמוסות קשיחות
لينڤيما 4 ملغ كبسولات صلبة
لينڤيما 10 ملغ كبسولات صلبة
Lenvatinib

2006391

PHARMA CODE
READ DIRECTION

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) which is stated on each blister and on the carton package. The expiry date refers to the last day of that month.
- Do not store at temperature above 25°C.
- Store in the original blister in order to protect from moisture.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Additional information:

In addition to the active ingredient, this medicine also contains:
Calcium carbonate, Low-substituted hydroxypropylcellulose, Microcrystalline cellulose (PH-101, PH-102), Mannitol, Hydroxypropylcellulose, Talc.
The capsule shell contains: Hypromellose, Titanium dioxide, Yellow iron oxide (E172), Red iron oxide (E172).
The printing ink contains: Black iron oxide (E172), Shellac, Propylene glycol, Potassium hydroxide.

What the medicine looks like and contents of the pack:

- LENVIMA 4 mg capsules have a yellowish-red body and yellowish-red cap, approximately 14.3 mm in length, marked in black ink with "€" on the cap, and "LENV 4 mg" on the body.
- LENVIMA 10 mg capsules have a yellow body and yellowish-red cap, approximately 14.3 mm in length, marked in black ink with "€" on the cap, and "LENV 10 mg" on the body.

The capsules are marketed in aluminum foil blisters in cartons of 30 capsules.

Registration Holder's name and importer : Eisai Israel ltd, PO Box 8049, Kfar Saba, 4418001, Israel

Drug registration numbers at the national medicines registry of the Ministry of Health:
LENVIMA 4 mg: 155-36-34514
LENVIMA 10 mg: 155-37-34530

Revised in February 2024 according to MOH guidelines.