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

Lenvima® 10 mg

The active ingredient and

Each hard capsule contains:

Lenvatinib (as mesilate) 10 mg

Hard Capsules

Composition:

its quantity:

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

Lenvima® 4 mg **Hard Capsules**

Composition: The active ingredient and its quantity: Each hard capsule contains:

Lenvatinib (as mesilate) 4 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

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:

X 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, Breastfeeding 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

to the skin

- 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
- you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel
- 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. The effects of LENVIMA in people younger than 18 years old are not

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

Early signs of kidney damage

- · 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 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

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 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 **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

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
- 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

- 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 recurrent endometrial 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

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

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 handfoot 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

If you have any further questions regarding the use of this edicine, 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

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

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
- 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) signs of a stroke, including feeling numb or weak on one side of your body, severe headache, seizure, confusion, difficulty talking
- 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 anal fistula (a small channel that forms between the anus and the surrounding skin) feeling bloated or having excess wind
- liver failure

feeling unwell

drowsiness, confusion, poor concentration, loss of consciousness that may be signs of liver failure inflammation of the gallbladde

Uncommon side effects: (affect up to 1 in 100 patients) painful infection or irritation near the anus

dry skin, thickening and itching of the skin

- 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 everolimu

- 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
- 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

urinary infections (increased frequency in urination and pain in

- **Common side effects:** (affect up to 1 in 10 patients)
- loss of body fluids (dehydration) feeling dizzy

passing urine)

- 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 unsual symptoms such as coughing when swallowing.
- 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

decreased secretion of hormones produced by adrenal glands

Side effect with unknown frequency: (the following side effects have

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

blood vessel wall (aneurysms and artery dissections).

- 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 cells underactive thyroid (tiredness, weight gain, constipation, feeling

cold, dry skin) and changes in blood test results for thyroid

changes in blood test results for magnesium (low) and changes

- stimulating hormone (high) changes in blood test results for potassium levels (low) and calcium levels (low)
- 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

back pain

joint or muscle pain

swelling of the legs

passing urine)

heart palpitations

low blood pressure

hair loss

· mini-stroke

surrounding skin)

feeling unwell

feeling very tired or weak

hoarse voice nausea and vomiting, constipation, diarrhoea, abdominal pain,

redness, soreness and swelling of the skin on the hands and feet

urinary infections (increased frequency in urination and pain in

heart problems or blood clots in the lungs (difficulty breathing,

breath, rapid or irregular heart rate, coughing, bluish colour to lips

chest pain) or other organs which may include chest pain or

pressure, pain in your arms, back, neck or jaw, being short of

decreased secretion of hormones produced by adrenal glands

signs of a stroke, including feeling numb or weak on one side of

your body, severe headache, seizure, confusion, difficulty talking,

severe difficulty breathing and chest pain, caused by a leak of air

anal fistula (a small channel that forms between the anus and the

other types of fistulae (an abnormal connection between different

as throat and windpipe). Symptoms would depend on where the

fistula is located. Talk to your doctor if you experience any new or

Not Known (the following side effects have been reported since the

known) an enlargement and weakening of a blood vessel wall or a tear

marketing of medicine but the frequency for them to occur is not

The following side effects may happen with this medicine when

changes in urine tests for protein (high) and urinary infections

(increased frequency in urination and pain in passing urine)

underactive thyroid (tiredness, weight gain, constipation,

feeling cold, dry skin) and changes in blood test results for

overactive thyroid (symptoms can include rapid heart rate,

changes in blood test results for potassium levels (low) and

changes in blood test results for magnesium levels (low) and

bleeding (most commonly nose bleeds, but also other types of

nausea and vomiting, constipation, diarrhoea, abdominal pain

redness, soreness and swelling of the skin on the hands and feet

bleeding such as blood in the urine, bruising, bleeding from the

dry, sore, or inflamed mouth, odd taste sensation

increase in amylase (enzyme involved in digestion)

blood clots in the lungs (difficulty breathing, chest pain)

decreased secretion of hormones produced by adrenal glands

signs of a stroke, including feeling numb or weak on one side of

signs of a heart problem, including chest pain or pressure, pain

in your arms, back, neck or jaw, being short of breath, rapid or

· headache, feeling confused, seizure, and changes in vision

increase in lipase (enzyme involved in digestion)

changes in blood test results for kidney function

changes in blood test results for liver function

(palmar-plantar erythrodysaesthesia)

Common (may affect up to 1 in 10 people)

loss of body fluids (dehydration)

inflammation of the pancreas

inflammation of the gallbladder

inflammation of the colon (colitis)

vision changes or feeling dizzy

Uncommon (may affect up to 1 in 100 people)

feeling bloated or having excess wind

low levels of platelets in the blood which may lead to bruising and

given in combination with pembrolizumab for advanced or

unsual symptoms such as coughing when swallowing.

in a blood vessel wall (aneurysms and artery dissections).

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

decrease in the number of white blood cells

decrease in the number of red blood cells

thyroid stimulating hormone (high)

recurrent cancer of the lining of the uterus:

difficulty in wound healing

sweating and weight loss)

cholesterol levels (high)

loss of appetite or weight loss

calcium levels (low)

feeling dizzy

gums or gut wall)

hoarse voice

high blood pressure

joint or muscle pain

trouble sleeping

heart palpitations

indigestion

kidney failure

feeling unwell

mini-stroke

hair loss

low blood pressure

feeling very tired or weak

headache

back pair

organs in the body or from the skin to an underlying structure such

from your lung into your chest so your lung cannot inflate

liver failure or signs of liver damage, including yellow skin or

yellowing of the whites of the eyes (jaundice) or drowsiness,

changes in blood test results for liver function

(palmar-plantar erythrodysaesthesia)

changes in urine tests for protein (high)

Common (may affect up to 1 in 10 people)

loss of body fluids (dehydration)

or fingers, and feeling very tired

inflammation of the colon (colitis)

inflammation of the gallbladder

vision changes or feeling dizzy

confusion, poor concentration

wound healing problems

feeling bloated or having excess wind

Uncommon (may affect up to 1 in 100 people)

painful infection or irritation near the anus

dry skin, thickening and itching of the skin

inflammation of the pancreas

- indigestion dry, sore, or inflamed mouth, odd taste sensation
 - severe difficulty breathing and chest pain, caused by a leak of air

feeling very tired

- from your lung into your chest so your lung cannot inflate increase in lipase and amylase (enzymes involved in digestion) painful infection or irritation near the anus
 - anal fistula (a small channel that forms between the anus and the

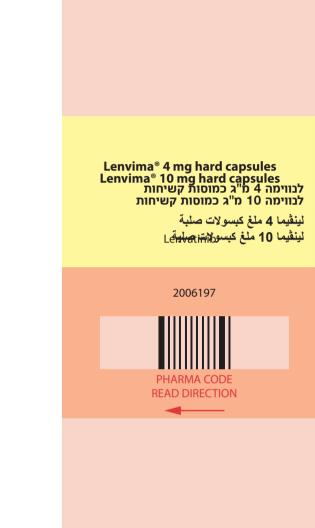
irregular heart rate, coughing, bluish colour to lips or fingers, and

- 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

changes in blood test results for kidney function and kidney failure 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



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

The capsule shell contains: Hypromellose, Titanium dioxide, Yellow iron

use. These measures will help to protect the environment 6. Additional information:

Hydroxypropylcellulose, Talc.

In addition to the active ingredient, this medicine also contains: Calcium carbonate, Low-substituted hydroxypropylcellulose, Microcrystalline cellulose (PH-101, PH-102), Mannitol,

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 yellowishred cap, approximately 14.3 mm in length, marked in black ink with "E" 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

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

LENVIMA 4 mg: 155-36-34514 LENVIMA 10 mg: 155-37-34530

Revised in September 2023 according to MOH guidelines. your body, severe headache, seizure, confusion, difficulty talking,

Drug registration numbers at the national medicines registry of the Ministry of Health: