Package leaflet: Information for the user

Lenvatinib 4 mg hard capsules
Lenvatinib 10 mg hard capsules

lenvatinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lenvatinib is and what it is used for
2. What you need to know before you take Lenvatinib
3. How to take Lenvatinib
4. Possible side effects
5. How to store Lenvatinib
6. Contents of the pack and other information

1 What Lenvatinib is and what it is used for

What Lenvatinib is
Lenvatinib is a medicine that contains the active substance lenvatinib. It is used in combination with pembrolizumab as the first treatment for adults with advanced kidney cancer (advanced renal cell carcinoma). It is also used in combination with everolimus to treat adults with advanced kidney cancer where other treatments (so-called "VEGF-targeted therapy") have not helped stop the disease.

How Lenvatinib works
Lenvatinib 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 Lenvatinib 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.

2 What you need to know before you take Lenvatinib

Do not take Lenvatinib if:
- you are allergic to lenvatinib or any of the other ingredients of this medicine (listed in section 6).
- you are breast-feeding (see the section below on Contraception, pregnancy and breast-feeding).

Warnings and precautions
Talk to your doctor before taking Lenvatinib if you:
- have high blood pressure
- are a woman able to become pregnant (see the section "Contraception, pregnancy and breast-feeding" below)

- have a history of heart problems or stroke
- have liver or kidney problems
- have had recent surgery or radiotherapy
- need to have a surgical procedure. Your doctor may consider stopping Lenvatinib if you will be undergoing a major surgical procedure as Lenvatinib may affect wound healing. Lenvatinib may be restarted once adequate wound healing is established.
- 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 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 Lenvatinib as bone damage in the jaw (osteonecrosis) has been reported in patients treated with Lenvatinib. If you need to undergo an invasive dental treatment or dental surgery, tell your dentist that you are being treated with Lenvatinib, 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.

Before taking Lenvatinib, 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 Lenvatinib. You may need to have additional treatment with other medicines, to take a lower dose of Lenvatinib, or to take extra care due to an increased risk of side effects.

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

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 section 4; Possible side effects).

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

Other medicines and Lenvatinib
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal preparations and medicines without a prescription.

Contraception, pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Use highly effective contraception while taking this medicine, and for at least one month after you finish treatment.
- Do not take Lenvatinib if you are planning to become pregnant during your treatment. This is because it may seriously harm your baby.

- If you become pregnant while being treated with Lenvatinib, tell your doctor immediately. Your doctor will help you decide whether the treatment should be continued.
- Do not breast-feed if you are taking Lenvatinib. This is because the medicine passes into breast milk and may seriously harm your breastfed baby.

Driving and using machines
Lenvatinib 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.

Lenvatinib contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3 How to take Lenvatinib

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
- The recommended daily dose of Lenvatinib is 20 mg once a day (two 10-mg capsules) in combination with pembrolizumab either 200 mg every 3 weeks or 400 mg every 6 weeks administered as an intravenous infusion over 30 minutes.
- The recommended daily dose of Lenvatinib is 18 mg once a day (one 10 mg capsule and two 4 mg capsules) in combination with one 5 mg tablet of everolimus once a day.
- If you have severe liver or kidney problems the recommended daily dose of Lenvatinib is 10 mg once a day (1 capsule of 10 mg) in combination with one 5 mg tablet of everolimus once a day. If you are receiving lenvatinib in combination with pembrolizumab, your doctor or pharmacist will check to see how much pembrolizumab you should receive.
- Your doctor may reduce your dose if you experience side effects.

Taking this medicine
- You can take the capsules with or without food.
- Do not open the capsules to avoid exposure to the contents of the capsule.
- Swallow the capsules whole with water.
- If you cannot swallow the capsules whole, you should use other medicines that contain lenvatinib.
- Take the capsules at about the same time each day.

How long to take Lenvatinib
You will usually carry on taking this medicine as long as you are getting benefit.

If you take more Lenvatinib than you should
If you take more Lenvatinib than you should, talk to a doctor or pharmacist straight away. Take the medicine pack with you.

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

What to do if you forget to take your dose depends on how long it is until your next dose.
- 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 the next dose at the normal time.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Tell your doctor straight away if you notice 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 of a severe increase in blood pressure.
– 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, feeling very tired – these may be signs of a heart problem, a blood clot in your 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 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.
– 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).

Tell your doctor straight away if you notice any of the side effects below.
The following side effects may happen with this medicine when given alone:

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 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 (may affect up to 1 in 10 people)

- 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, vision changes or feeling dizzy
- 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
- drowsiness, confusion, poor concentration, loss of consciousness that may be signs of liver failure
- inflammation of the gallbladder
- dry skin, thickening and itching of the skin
- feeling unwell
- a hole (perforation) in the stomach or intestines

Uncommon (may affect up to 1 in 100 people)
- 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

Rare (may affect up to 1 in 1,000 people)
- Tumour lysis syndrome (TLS)

Not known (frequency cannot be estimated from the available data)

- 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 doctor if you experience any new or unsual symptoms such as coughing when swallowing.

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

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 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 (may affect up to 1 in 10 people)
- urinary infections (increased frequency in urination and pain in passing urine)
- loss of body fluids (dehydration)
- feeling dizzy
- 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
- 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 bloated or having excess wind

- inflammation of the gallbladder
- hair loss
- feeling unwell
- a hole (perforation) in the stomach or intestines

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
- 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.
- decreased secretion of hormones produced by adrenal glands

Rare (may affect up to 1 in 1,000 people)
- Tumour lysis syndrome (TLS)

Not known (frequency cannot be estimated from the available data)
- 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:

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 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 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
- 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
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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 unsual symptoms such as coughing when swallowing.

Rare (may affect up to 1 in 1,000 people)
- Tumour lysis syndrome (TLS)

Not known (frequency cannot be estimated from the available data)

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Lenvatinib

– Keep this medicine out of the sight and reach of children.
– Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.
– Store in the original package in order to protect from moisture.
– Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Lenvatinib contains
– The active substance is lenvatinib.
  – Lenvatinib 4 mg hard capsules: - Each hard capsule contains 4 mg of lenvatinib (as besilate).
  – Lenvatinib 10 mg hard capsules: - Each hard capsule contains 10 mg of lenvatinib (as besilate).
– The other ingredients are sodium hydrogen carbonate, mannitol, microcrystalline cellulose, hydroxypropylcellulose, low-substituted hydroxypropylcellulose, talc.
– The capsule shell of the 4 mg capsules contains hypromellose, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).
– The capsule shell of the 10 mg capsules contains hypromellose, titanium dioxide, iron oxide yellow (E172).
– The capsule cap contains hypromellose, titanium dioxide, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).
– The printing ink contains shellac, iron oxide black (E172), potassium hydroxide.

What Lenvatinib looks like and contents of the pack
– The 4 mg hard capsule (capsule) is a caramel opaque body and caramel opaque cap, size 4 (approximately 14.3 mm in length), printed with "L7VB" over "4".
– The 10 mg hard capsule (capsule) is a yellow opaque body and caramel opaque cap, size 4 (approximately 14.3 mm in length), printed with "L7VB" over "10".
– Each carton contains 30, 60 or 90 hard capsules in oPA/Al/PVC/Al blisters or 30x1, 60x1 or 90x1 hard capsules in oPA/Al/PVC/Al unit dose blisters.
– Each carton contains 30, 60 or 90 hard capsules in oPA/Al/PVC/PE/Al blisters with desiccant or 30x1, 60x1 or 90x1 hard capsules in oPA/Al/PVC/PE/Al unit dose blisters with desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Viatris Limited
Damastown Industrial Park

Mulhuddart
Dublin 15
DUBLIN
Ireland

Manufacturer(s):
Synthon Hispania S.L.
Calle De Castello 1
Sant Boi De Llobregat
Barcelona
08830
Spain

or

Synthon B.V.
Microweg 22
Nijmegen
Gelderland
6545 CM
Netherlands

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria, Germany:	Lenvatinib RCC Viatris 4 mg and 10 mg Hartkapseln
Bulgaria:	Ленватиниб Майлан 4 mg and 10 mg твърди капсули
Czech Republic:	Lenvatinib Viatris Pharma
Denmark, Italy:	Lenvatinib Mylan
Portugal:	Lenvatinib RCC Viatris
Finland:	Lenvatinib Mylan 4 mg and 10 mg kapseli, kova
France:	Lenvatinib Viatris CCR 4 mg and 10 mg, gélule
Ireland:	Lenvatinib 4 mg and 10 mg hard capsules
Luxembourg:	Lenvatinib Mylan 4 mg and 10 mg
Netherlands:	Lenvatinib Mylan 4 mg and 10 mg, harde capsules
Norway:	Lenvatinib Mylan 4 mg and 10 mg kapsler, harde
Sweden:	Lenvatinib Mylan 4 mg and 10 mg hårda kapslar

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