Package leaflet: Information for the patient

Cabozantinib Ipsen 20 mg film-coated tablets
Cabozantinib Ipsen 40 mg film-coated tablets
Cabozantinib Ipsen 60 mg film-coated tablets
cabozantinib

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Cabozantinib Ipsen is and what it is used for

What Cabozantinib Ipsen is

Cabozantinib Ipsen is a cancer medicine that contains the active substance cabozantinib.
It is used in adults to treat:
- advanced kidney cancer called advanced renal cell carcinoma
- liver cancer when a specific anticancer medicine (sorafenib) is no longer stopping the disease from progressing.
- Advanced neuroendocrine tumours – tumours that originate from the pancreas, stomach, bowels, lung or other organs. It is given when patients with these tumours no longer respond to a previous treatment option.

Cabozantinib Ipsen is also used to treat locally advanced or metastatic differentiated thyroid cancer, a type of cancer in the thyroid gland, in adults when radioactive iodine and anticancer medicine treatments are no longer stopping the disease from progressing.

Cabozantinib Ipsen may be given in combination with nivolumab for advanced kidney cancer. It is important that you also read the package leaflet of nivolumab. If you have any questions about these medicines, please ask your doctor.

How Cabozantinib Ipsen works

Cabozantinib Ipsen blocks the action of proteins called receptor tyrosine kinases (RTKs), which are involved in the growth of cells and the development of new blood vessels that supply them. These proteins can be present in high amounts in cancer cells, and by blocking their action this medicine can slow down the rate at which the tumour grows and help to cut off the blood supply that the cancer needs.

2. What you need to know before you take Cabozantinib Ipsen

Do not take Cabozantinib Ipsen

- if you are allergic to cabozantinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cabozantinib Ipsen if you:

- have high blood pressure
- have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall
- have diarrhoea
- have a recent history of significant bleeding
- have had surgery within the last month (or if surgical procedures are planned), including dental surgery
- have inflammatory bowel disease (for example, Crohn's disease or ulcerative colitis, diverticulitis, or appendicitis)
- have a recent history of blood clot in the leg, stroke, or heart attack
- have heart failure (can include symptoms like shortness of breath, feeling tired, fainting, swollen ankles and legs)
- have thyroid problems. Tell your doctor if you get tired more easily, generally feel colder than other people, or your voice deepens whilst taking this medicine.
- have liver or kidney disease.

Tell your doctor if any of these affect you.

You may need treatment for them, or your doctor may decide to change your dose of Cabozantinib Ipsen or stop treatment altogether. See also section 4 "*Possible side effects"*.
You should also tell your dentist that you are taking this medicine. It is important for you to practice good mouth care during treatment.

Children and adolescents

Cabozantinib Ipsen is not recommended for children or adolescents. The effects of this medicine in people younger than 18 years old are not known.

Other medicines and Cabozantinib Ipsen

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Cabozantinib Ipsen can affect the way some other medicines work. Also, some medicines can affect the way Cabozantinib Ipsen works. This could mean that your doctor needs to change the dose(s) that you take. You should tell your doctor about every medicine, but in particular if taking:

- Medicines that treat fungal infections, such as itraconazole, ketoconazole and posaconazole
- Medicines used to treat bacterial infections (antibiotics) such as erythromycin, clarithromycin, and rifampicin
- Allergy medicines such as fexofenadine
- Medicines to treat angina pectoris (chest pain owing to inadequate supply to the heart) such as ranolazine
- Medicines used to treat epilepsy or fits such as phenytoin, carbamazepine, and phenobarbital
- Herbal preparations containing St. John's Wort *(Hypericum perforatum),* sometimes used for treating depression or depression-related conditions such as anxiety
- Medicines used to thin the blood, such as warfarin and dabigatran etexilate

- Medicines to treat high blood pressure or other heart conditions, such as aliskiren, ambrisentan, digoxin, talinolol, and tolvaptan
- Medicines for diabetes, such as saxagliptin and sitagliptin
- Medicines used to treat gout, such as colchicine
- Medicines used to treat HIV or AIDS, such as efavirenz, ritonavir, maraviroc and emtricitabine
- Medicines used to prevent transplant rejection (ciclosporin) and ciclosporin-based regimens in rheumatoid arthritis and psoriasis

Cabozantinib Ipsen with food

Avoid consuming grapefruit-containing products for as long as you are using this medicine, as they may increase the levels of Cabozantinib Ipsen in your blood.

Pregnancy, breast-feeding and fertility

Avoid becoming pregnant while being treated with Cabozantinib Ipsen . If you or your partner could become pregnant, use adequate contraception during treatment and for at least 4 months after treatment has finished. Talk to your doctor about which methods of contraception are appropriate while you are taking this medicine (see also under Other medicines and Cabozantinib Ipsen , above).

Tell your doctor if you or your partner become pregnant or plan to become pregnant while you are being treated with this medicine.

Talk to your doctor BEFORE taking this medicine if you or your partner are considering or planning to have a baby after your treatment has finished. There is a possibility your fertility could be affected by treatment with this medicine.

Women taking this medicine should not breast-feed during treatment and for at least 4 months after treatment has finished, as cabozantinib and/or its metabolites may be excreted in breast milk and be harmful to your child.

If you take this medicine whilst using oral contraceptives, the oral contraceptives may be ineffective. You should also use a barrier contraceptive (e.g. condom or diaphragm) whilst taking this medicine and for at least 4 months after treatment has finished.

Driving and using machines

Use caution when driving or using machines. Keep in mind that treatment with Cabozantinib Ipsen may make you feel tired or weak and can affect your ability to drive or use machines.

Cabozantinib Ipsen contains lactose
This medicine contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Cabozantinib Ipsen contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Cabozantinib Ipsen

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

You should continue to take this medicine until your doctor decides to stop your treatment. If you get serious side effects, your doctor may decide to change your dose or stop treatment earlier than originally planned. Your doctor will tell you if you need your dose adjusted.

Cabozantinib Ipsen should be taken once a day. The usual dose is 60 mg, however your doctor will decide on the right dose for you.
When this medicine is given in combination with nivolumab for the treatment of advanced kidney cancer, the recommended dose of Cabozantinib Ipsen is 40 mg once a day.

You should not take Cabozantinib Ipsen with food. You should not eat anything for at least 2 hours before and for 1 hour after taking the medicine. Swallow the tablet with a full glass of water. Do not crush the tablets.

If you take more Cabozantinib Ipsen than you should

If you have taken more of this medicine than you have been instructed to, talk to a doctor or go to the hospital with the tablets and this leaflet straight away.

If you forget to take Cabozantinib Ipsen

- If there are still 12 hours or more before your next dose is due, then take the missed dose as soon as you remember. Take the next dose at the normal time.
- If your next dose is due in less than 12 hours, then do not take the dose that you have missed. Take your next dose at the normal time.

If you stop using Cabozantinib Ipsen
Stopping your treatment may stop the effect of the medicine. Do not stop treatment with this medicine unless you have discussed this with your doctor.

When this medicine is given in combination with nivolumab, you will first be given nivolumab followed by Cabozantinib Ipsen .

Please refer to the package leaflet of nivolumab in order to understand the use of this medicine. If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get side effects, your doctor may tell you to take Cabozantinib Ipsen at a lower dose. Your doctor may also prescribe other medicines to help control your side effects.

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

- Symptoms including pain in the abdomen, nausea (feeling sick), vomiting, constipation, or fever. These may be signs of a gastrointestinal perforation, a hole that develops in your stomach or intestine that could be life-threatening. Gastrointestinal perforation is common (it may affect up to 1 in 10 people).
- Severe or uncontrollable bleeding with symptoms such as: vomiting blood, black stools, bloody urine, headache, coughing up blood. It is common (it may affect up to 1 in 10 people).

- Feeling drowsy, confused or loss of consciousness. This may be due to liver problems which are common (they may affect up to 1 in 10 people).
- Swelling, or shortness of breath. These are very common (they may affect more than 1 in 10 people).
- A wound that does not heal. It is uncommon (it may affect 1 in 100 people).
- Fits, headaches, confusion, or finding it difficult to concentrate. These may be signs of a condition called posterior reversible encephalopathy syndrome (PRES). PRES is uncommon (it may affect 1 in 100 people).
- 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). It is uncommon (it may affect 1 in 100 people).

Other side effects with Cabozantinib Ipsen alone include:

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

- Anaemia (low levels of red blood cells which carry oxygen), low levels of platelets (cells which help the blood to clot)
- Reduced thyroid activity; symptoms can include tiredness, weight gain, constipation, feeling cold and dry skin
- Decreased appetite, altered sense of taste
- Decreased amount of magnesium,potassium or calcium in the blood
- Decreased amount of protein albumin in blood (which carries substances such as hormones, medicines, and enzymes throughout your body)
- Headache, dizziness
- High blood pressure (hypertension)
- Bleeding
- Difficulty in speaking, hoarseness (dysphonia), cough and shortness of breath
- Stomach upset, including diarrhoea, nausea, vomiting, constipation, indigestion and abdominal pain
- Redness, swelling or pain in the mouth or throat (stomatitis)
- Skin rash sometimes with blisters, itching, pain of the hands or soles of the feet, rash
- Pain in the arms, hands, legs or feet, pain in joints
- Feeling tired or weak, inflammation of the oral and gastrointestinal mucosa, swelling in your legs and arms
- Weight loss
- Abnormal liver function tests (increased amounts of the liver enzymes aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase)

Common side effects (may affect up to 1 in 10 people)

- Abscess (collection of pus, with swelling and inflammation)
- Dehydration
- Decreased amount of phosphate and sodium in the blood
- Increased amount of potassium in the blood
- Increased amount of the waste product bilirubin in the blood (which may result in jaundice/yellow skin or eyes)
- High (hyperglycaemia) or low (hypoglycaemia) sugar levels in the blood
- Inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs)
- Ringing in ears (tinnitus)
- Blood clots in the veins, low blood pressure (hypotension)
- Blood clots in the lungs, inflammation of the lining of the nose (allergic rhinitis)
- Inflammation of the pancreas, a painful tear or abnormal connection of the tissues in your body (fistula), gastro-oesophageal reflux disease (bringing up stomach acid), haemorrhoids (piles), dry mouth and pain in the mouth, difficulty in swallowing, flatulence

- Severe itching of skin, alopecia (hair loss and thinning), dry skin, acne, hair colour change, thickening of the skin outer layer, redness of the skin
- Muscle spasms
- Protein in urine (seen in tests)
- Abnormal liver function tests (increased amounts of the liver enzyme gamma-glutamyl transferase in your blood)
- Abnormal kidney function tests (increased amounts of creatinine in your blood)
- Increased level of the enzyme that breaks down fats (lipase) and of the enzyme that breaks down starch (amylase)
- Increase in cholesterol or triglyceride levels in the blood
- Low levels of white blood cells (which are important in fighting infection)
- Lung infection (pneumonia)

Uncommon side effects (may affect 1 in 100 people)

- Fits, stroke
- Severe high blood pressure
- Blood clots in the arteries
- Decrease in bile flow from the liver
- A burning or painful sensation in the tongue (glossodynia)
- Heart attack
- Heart failure (can include symptoms like shortness of breath, feeling tired, fainting, swollen ankles and legs)
- Clot/ embolus that travelled through your arteries and become stuck
- Collapsed lung with air trapped in the space between the lung and chest, often causing shortness of breath (pneumothorax)

Not known (proportion of people affected not known)

- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)
- Inflammation of the blood vessels in the skin (cutaneous vasculitis)

The following side effects have been reported **with Cabozantinib Ipsen in combination with nivolumab:**

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

- Infections of the upper respiratory tract
- Reduced thyroid activity; symptoms can include tiredness, weight gain, constipation, feeling cold and dry skin
- Increased thyroid activity; symptoms can include rapid heart rate, sweating and weight loss
- Decreased appetite, altered sense of taste
- Headache, dizziness
- High blood pressure (hypertension)
- Difficulty in speaking, hoarseness (dysphonia), cough and shortness of breath
- Stomach upset, including diarrhoea, nausea, vomiting, indigestion, abdominal pain and constipation
- Redness, swelling or pain in the mouth or throat (stomatitis)
- Skin rash sometimes with blisters, itching, pain of the hands or soles of the feet, rash or severe itching of skin
- Pain in joints (arthralgia), muscle spasm, muscle weakness and aching muscles
- Protein in the urine (seen in test)
- Feeling tired or weak, fever and oedema (swelling)
- Abnormal liver function tests (increased amounts of the liver enzymes aspartate aminotransferase, alanine aminotransferase or alkaline phosphatase in your blood, higher blood levels of the waste product bilirubin)

- Abnormal kidney function tests (increased amounts of creatinine in your blood)
- High (hyperglycaemia) or low (hypoglycaemia) sugar levels in the blood
- Anaemia (low levels of red blood cells which carry oxygen), low levels of white blood cells (which are important in fighting infection), low levels of platelets (cells which help the blood to clot)
- An increased level of the enzyme that breaks down fats (lipase) and of the enzyme that breaks down starch (amylase)
- Decreased amount of phosphate
- Increased or decreased amount of potassium
- Decreased or increased blood levels of calcium, magnesium, or sodium
- Decrease in body weight

Common side effects (may affect up to 1 in 10 people)

- Serious lung infection (pneumonia)
- Increase in some white blood cells called eosinophils
- Allergic reaction (including anaphylactic reaction)
- Decreased secretion of hormones produced by adrenal glands (glands situated above the kidneys)
- Dehydration
- Inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs)
- Ringing in ears (tinnitus)
- Dry eyes and blurred vision
- Changes in the rhythm or rate of the heartbeat, fast heart rate
- Blood clots in the blood vessels
- Inflammation of the lungs (pneumonitis, characterised by coughing and difficulty breathing), blood clots in the lung, fluid around the lungs
- Nose bleeding
- Inflammation of the colon (colitis), dry mouth, pain in the mouth, inflammation of the stomach (gastritis) and haemorrhoids (piles)
- Inflammation of the liver (hepatitis)
- Dry skin and redness of the skin
- Alopecia (hair loss and thinning), hair colour change
- Inflammation of the joints (arthritis)
- Kidney failure (including abrupt loss of kidney function)
- Pain, chest pain
- Increase in triglyceride levels in the blood
- Increase in cholesterol levels in the blood

Uncommon side effects (may affect 1 in 100 people)

- Allergic reactions related to the infusion of the medicine nivolumab
- Inflammation of the pituitary gland situated at the base of the brain (hypophysitis), swelling of the thyroid gland (thyroiditis)
- A temporary inflammation of the nerves that causes pain, weakness and paralysis in the extremities (Guillain Barré syndrome); muscle weakness and tiredness without atrophy (myasthenic syndrome)
- Inflammation of the brain
- Inflammation of the eye (which causes pain and redness)
- Inflammation of the heart muscle
- Clot/ embolus that travelled through your arteries and become stuck
- Inflammation of the pancreas (pancreatitis), intestinal perforation, burning or painful sensation in the tongue (glossodynia)
- Skin disease with thickened patches of red skin, often with silvery scales (psoriasis)
- Hives (itchy rash)

- Muscle tenderness of weakness, not caused by exercise (myopathy), bone damage in the jaw, painful tear or abnormal connection of the tissues in your body (fistula)
- Inflammation of the kidney
- Collapsed lung with air trapped in the space between the lung and chest, often causing shortness of breath (pneumothorax)

Not known (proportion of people affected not known)

- Inflammation of the blood vessels in the skin (cutaneous vasculitis)
- Progressive destruction and loss of intrahepatic bile ducts and jaundice

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 via the national reporting system (see details below).
By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Cabozantinib Ipsen

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 bottle label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Cabozantinib Ipsen contains

The active substance is cabozantinib (*S*)-malate.

Cabozantinib Ipsen 20 mg film-coated tablets: Each tablet contains cabozantinib (*S*)-malate equivalent to 20 mg of cabozantinib.
Cabozantinib Ipsen 40 mg film-coated tablets: Each tablet contains cabozantinib (*S*)-malate equivalent to 40 mg of cabozantinib.
Cabozantinib Ipsen 60 mg film-coated tablets: Each tablet contains cabozantinib (*S*)-malate equivalent to 60 mg of cabozantinib.

The other ingredients are:

- **Tablet contents:** microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide anhydrous, magnesium stearate. (see section 2 for lactose content)
- **Film coating:** hypromellose, titanium dioxide (E171), triacetin, iron oxide yellow (E172)

What Cabozantinib Ipsen looks like and contents of the pack

Cabozantinib Ipsen 20 mg film-coated tablets are yellow, round with no score, and identified with "XL" on one side and "20" on the other side.
Cabozantinib Ipsen 40 mg film-coated tablets are yellow, triangle shaped with no score, and identified with "XL" on one side and "40" on the other side.
Cabozantinib Ipsen 60 mg film-coated tablets are yellow, oval shaped with no score, and identified with "XL" on one side and "60" on the other side.

Cabozantinib Ipsen is available in packs containing one plastic bottle with 30 film-coated tablets. The bottle contains three silica gel desiccant canisters and a polyester coil to prevent damage to the film-coated tablets. Keep the canisters and the polyester coil in the bottle and do not swallow the desiccant canisters.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last revised in February 2026.

Other sources of information

Is this leaflet hard to see or read? Please phone +44 (0) 1753 627777 and ask for help.