

- ▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems

CABOMETRYX™

20mg, 40mg and 60 mg Tablets

cabozantinib

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about CABOMETRYX.

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

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT CABOMETYX IS USED FOR

CABOMETYX is used to treat a certain type of kidney cancer called renal cell carcinoma (RCC) in adults who have already had previous treatment.

It contains the active ingredient cabozantinib (S)-malate.

It is a multi-kinase inhibitor.

It works by blocking 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 CABOMETYX can slow down the rate at which the tumour grows and help to cut off the blood supply that the cancer needs.

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

Your doctor may have prescribed it for another reason.

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

BEFORE YOU TAKE CABOMETYX

When you must not take it

Do not take CABOMETYX if you have an allergy to:

- cabozantinib, the active ingredient in CABOMETYX
- any of the other ingredients listed at the end of this leaflet under Product Description

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

CABOMETYX tablets contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking Cabometyx.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

You should avoid becoming pregnant while being treated with CABOMETYX.

CABOMETYX should not be taken during pregnancy. Your doctor will discuss the risks with you.

If you or your partner could become pregnant, you must use a safe and effective form of contraception (such as a condom or coil) to avoid becoming pregnant while you are being treated with CABOMETYX. You should also do this for at least 4 months after stopping treatment. Discuss with your doctor what may be appropriate contraception for you.

Tell your doctor if you are taking oral contraceptives.

If you take CABOMETYX whilst using oral contraceptives, the oral contraceptives may be ineffective.

You should not breastfeed while taking CABOMETYX 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.

Tell your doctor if you or your partner plan to become pregnant in the future.

CABOMETRYX may affect your fertility.

CABOMETRYX is not recommended for children or adolescents.

The effects of CABOMETRYX in people younger than 18 years old are not known.

Tell your doctor if you:

- have high blood pressure
- 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 liver or kidney disease.

- have a pre-existing heart condition, slow heart rate or are taking medicine to prevent abnormal heart rhythm.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking CABOMETYX.

You may need treatment for them, or your doctor may decide to change your dose of CABOMETYX, or stop treatment altogether.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

This is because CABOMETYX can affect the way some other medicines work. Also, some medicines can affect the way CABOMETYX 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 and 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 ambrisentan, digoxin, 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
- Medicines used for contraception such as oral contraceptives

You may need to use different amounts of your medicine. Your doctor will be able to advise you. Your doctor and pharmacist will have a complete list of medicines to be careful of and to avoid while taking CABOMETYX.

You should tell your doctor if you are taking oral contraceptives.

If you take CABOMETRYX whilst using oral contraceptives, the oral contraceptives may be ineffective.

HOW TO TAKE CABOMETRYX

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

The usual dose of CABOMETRYX is 60 mg taken once a day. Your doctor will decide on the right dose for you.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

How to take it

Swallow the tablet whole with a full glass of water. Do not crush the tablets.

CABOMETRYX should not be taken with food. You should not eat anything for at least 2 hours before taking CABOMETRYX and for 1 hour after taking the medicine.

When to take CABOMETYX

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take CABOMETYX

Continue taking your medicine for as long as your doctor tells you.

Do not stop unless your doctor advises you 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.

If you forget to take it

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. Wait until your next dose, and then continue to take it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CABOMETYX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING CABOMETYX

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking CABOMETYX.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking CABOMETYX.

It may affect other medicines used during surgery.

If you become pregnant while taking CABOMETRYX, tell your doctor immediately.

Do not stop treatment without first discussing it with your doctor.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take CABOMETRYX to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Use caution when driving or operating machines.

Treatment with CABOMETRYX may make you feel tired or weak and can affect your ability to drive or operate machines.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CABOMETRYX

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

The following side effects can be serious and you should tell your doctor immediately or go to a hospital if you experience any of them:

- Symptoms including pain in the abdomen (belly), 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.
- Severe or uncontrollable bleeding with symptoms such as: vomiting blood, black stools, bloody urine, headache, coughing up of blood.
- Swelling, pain in your hands and feet, or shortness of breath.
- A wound that does not heal.
- Fits, headaches, confusion, or finding it difficult to concentrate. These may be signs of a condition called reversible posterior leukoencephalopathy syndrome (RPLS). RPLS is uncommon (it affects less than 1 in 100 people).

You may experience the following side effects with this medicine. Tell the doctor if you have any of the following:

Very common side effects of CABOMETYX (more than 1 in 10 patients) are:

- Stomach upset, including diarrhoea, nausea, vomiting, constipation, indigestion, and abdominal pain
- Blisters, pain of the hands or soles of the feet, rash or redness of the skin, dry skin
- Decreased appetite, weight loss, altered sense of taste
- Fatigue, weakness, headache, dizziness
- Hypertension (increase in blood pressure)
- Anaemia (low levels of red blood cells)
- Redness, swelling or pain in the mouth or throat, difficulty in speaking, hoarseness, cough
- Changes in blood tests used to monitor general health and function of your organs (including the liver), low levels of electrolytes (like magnesium, calcium, sodium, or potassium)
- Increase in the level of bilirubin in your blood (which may result in jaundice/yellow skin or eyes)
- Pain in arms, legs and joints, muscle spasms
- Shortness of breath
- Protein in urine (seen in tests)

- Reduced thyroid activity; symptoms can include: tiredness, weight gain, constipation, feeling cold and dry skin

Common side effects of CABOMETYX (more than 1 in a 100 patients) are:

- Abscess (collection of pus, with swelling and inflammation)
- Dehydration (lack of fluids)
- Ringing in ears
- Blood clots in the lungs
- Pain in the upper part of the abdomen
- Gastro-oesophageal reflux disease (bringing up stomach acid)
- Haemorrhoids (piles)
- Alopecia (hair loss and thinning)
- Swelling in your legs, feet, arms and hands

Uncommon side effects of CABOMETYX (between 1 in a 100 and 1 in a 1000 patients) are:

- Fits
- A painful tear or abnormal connection of the tissue in your anus

- Inflammation of the pancreas
- Decrease in bile flow from the liver
- Bone damage in the jaw

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

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

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

AFTER TAKING CABOMETRYX

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Store your tablets in a cool, dry place where the temperature stays below 25°C.

Do not store CABOMETRYX or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

CABOMETRYX 20 mg film-coated tablets are yellow, round with no score, and identified with "XL" on one side and "20" on the other side.

CABOMETRYX 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.

CABOMETRYX 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.

Ingredients

Active ingredient:

- Cabozantinib as cabozantinib (S) -malate

Excipient Ingredients:

- microcrystalline cellulose,
- lactose,
- hypromellose,
- croscarmellose sodium,
- colloidal anhydrous silica
- magnesium stearate.
- hypromellose,
- titanium dioxide,
- triacetin
- iron oxide yellow

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

SPONSOR

Ipsen Pty Ltd

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Glen Waverley

Victoria 3150

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Australian Register Number(s)

CABOMETYX 20 mg film coated tablet: AUST R 283800

CABOMETYX 40 mg film coated tablet: AUST R 283801

CABOMETYX 60 mg film coated tablet: AUST R 283799

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