Cabometyx®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using CABOMETYX?

CABOMETYX contains the active ingredient cabozantinib. CABOMETYX is used to treat patients with advanced kidney cancer (advanced renal cell carcinoma), liver cancer, a type of thyroid cancer called differentiated thyroid cancer, or a type of cancer known as neuroendocrine tumours of the pancreas, stomach, intestine, lung, or other parts of the body.
For more information, see Section 1. Why am I using CABOMETYX? in the full CMI.

2. What should I know before I use CABOMETYX?

Do not use if you have ever had an allergic reaction to cabozantinib or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or breastfeeding, or plan to become pregnant. For more information, see Section 2. What should I know before I use CABOMETYX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CABOMETYX and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CABOMETYX?

- The usual dose is 60 mg taken once a day. Your doctor will decide on the right dose for you.
- CABOMETYX should not be taken with food. Grapefruit juice should be avoided while using this medicine.

More instructions can be found in Section 4. How do I use CABOMETYX? in the full CMI.

5. What should I know while using CABOMETYX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using CABOMETYX. • Tell your doctor immediately if you become pregnant.
Things you should not do	• Do not stop using this medicine suddenly. • Do not take CABOMETYX 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.
Driving or using machines	• Treatment with CABOMETYX may make you feel tired or weak and can affect your ability to drive or operate machines.
Looking after your medicine	• Keep your medicine in the original container in a cool, dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using CABOMETYX? in the full CMI.

6. Are there any side effects?

Like all medicines, CABOMETYX can cause side effects, although not everybody gets them. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI. Tell your doctor straight away if you notice any of the following side effects, you may need urgent medical attention:

- pain in the abdomen (belly), feeling sick, vomiting, constipation, fever. These may be signs of a hole that develops in your stomach or intestine (common).
- vomiting blood, black stools, bloody urine, headache, coughing up blood. These may be signs of severe bleeding inside your body (very common).
- swelling, pain in your hands and feet, or shortness of breath. These may be signs of blood clots or oedema (common).
- feeling drowsy or confused, loss of consciousness. These may be signs of liver problems (common).
- coughing, difficulty breathing. These may be signs of a lung infection (common).
- kidney failure including abrupt loss of kidney function (common).

▼ This medicine is subject to additional monitoring. 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.

Cabometyx®

Active ingredient(s): *cabozantinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CABOMETYX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CABOMETYX.**

Where to find information in this leaflet:

1. Why am I using CABOMETYX?
2. What should I know before I use CABOMETYX?
3. What if I am taking other medicines?
4. How do I use CABOMETYX?
5. What should I know while using CABOMETYX?
6. Are there any side effects?
7. Product details

1. Why am I using CABOMETYX?

CABOMETYX contains the active ingredient cabozantinib (as cabozantinib (S)-malate). CABOMETYX 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.

CABOMETYX is used to treat:

- advanced stages of a type of kidney cancer called renal cell carcinoma (RCC)
- liver cancer in adults who have been previously treated with a specific anticancer medicine (sorafenib)
- a type of thyroid cancer called differentiated thyroid cancer (DTC), in adults and children 12 years of age and older, that has spread (locally advanced or metastatic), and,
- has progressed after treatment with a medicine called VEGFR-targeted treatment, and,
- when the DTC can no longer be treated with radioactive iodine, or patients are not able to receive radioactive iodine treatment.
- neuroendocrine tumours (NET) of the pancreas, stomach, intestine, lung, or other parts of the body, after you have received previous treatment.

CABOMETYX may also be given in combination with another medicine called nivolumab to treat advanced kidney cancer (RCC). It is important that you also read the Consumer Medicine Information of nivolumab.

2. What should I know before I use CABOMETYX?

Warnings

Do not use CABOMETYX if:

- you are allergic to cabozantinib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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

Check with your doctor if you:

- have high blood pressure. This could increase the risk of heart failure when taking this medicine.
- have, or have had, an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- 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.
- have diarrhoea.
- have intolerance to some sugars. The tablets contain lactose.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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.

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

CABOMETYX may affect your fertility.

Children and Teenagers

- CABOMETYX is not recommended for children or adolescents for treatment of liver or kidney cancer.
- CABOMETYX can be used to treat children and adolescents 12 years of age or older with a type of thyroid cancer (DTC).
- It is not known if CABOMETYX is safe and effective in children younger than 12 years of age.

3. What if I am taking other medicines?

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

Some medicines may interfere with CABOMETYX and affect how it works.

You should tell your doctor about every medicine, but in particular if you are 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 blood 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 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, as they may be ineffective whilst using CABOMETYX.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CABOMETYX.

4. How do I use CABOMETYX?

How much to take

- The usual dose of CABOMETYX is 60 mg taken once a day.
- When CABOMETYX is given in combination with nivolumab for the treatment of advanced kidney cancer, the recommended dose of CABOMETYX is 40 mg once a day.
- Your doctor will decide on the right dose for you depending on the type of cancer that CABOMETYX is being used to treat.
- Follow your doctor's instructions and use CABOMETYX until your doctor tells you to stop.

How to take CABOMETYX

- Swallow the tablet whole with a full glass of water.
- Do not crush the tablets.
- CABOMETYX should not be taken with food. You should not eat anything for at least 2 hours before taking CABOMETYX and for 1 hour after taking the medicine.
- Avoid consuming grapefruit juice or grapefruit-containing products for as long as you are using this medicine, as they may increase the levels of CABOMETYX in your blood.

When to take CABOMETYX

- CABOMETYX should be taken at about the same time each day.
- When CABOMETYX is given in combination with nivolumab, you will first be given nivolumab followed by CABOMETYX.
- Continue taking your medicine for as long as your doctor tells you.

If you forget to use CABOMETYX

CABOMETYX should be used regularly at the same time each day. If there are still 12 hours or more before your next dose is due, then take the missed dose as soon as you remember.

If your next dose is due in less than 12 hours, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much CABOMETYX

If you think that you have used too much CABOMETYX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CABOMETYX?

Things you should do

Call your doctor straight away if you:

- Experience any of the symptoms under Serious Side Effects in Section 6.

Remind any doctor or pharmacist you visit that you are using CABOMETYX.

You should also tell your dentist that you are taking CABOMETYX. It is important for you to practice good mouth care during treatment with 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 CABOMETYX, 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 should not do

- Do not stop using this medicine suddenly.
- Do not take CABOMETYX 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CABOMETYX affects you.

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

Looking after your medicine

- 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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
Signs of severe or uncontrollable bleeding inside your body: • vomiting blood • black stools • bloody urine • headache • coughing up blood **Signs of a gastrointestinal perforation, a hole that develops in your stomach or intestine:** • pain in the abdomen (belly) • nausea (feeling sick) • vomiting • constipation • fever **Gastrointestinal/muscle related:** • A painful tear or abnormal connection of the tissues in your body (fistula) **Signs of liver problems:** • feeling drowsy or confused • loss of consciousness **Signs of lung infection:** • Serious lung infection (pneumonia)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• Inflammation of the lungs (pneumonitis, characterised by coughing and difficulty breathing), blood clots in the lung **Signs of kidney problems:** • Kidney failure (including abrupt loss of kidney function) **Signs of a condition called posterior reversible encephalopathy syndrome (PRES):** • fits • headaches • confusion • finding it difficult to concentrate **Signs of bone damage in the jaw (osteonecrosis):** • pain in the mouth, teeth and/or jaw • swelling or sores inside the mouth • numbness or a feeling of heaviness in the jaw • loosening of a tooth **Heart or circulatory system related:** • Changes in the rhythm or rate of the heartbeat, fast heart rate, inflammation of the heart muscle (myocarditis) **Nervous system related:** • A temporary inflammation of the nerves that causes pain, weakness and paralysis in the extremities (Guillain Barré syndrome) • Inflammation of the brain (encephalitis) **Other serious side effects:** • Swelling, pain in your hands and feet, or shortness of breath. • Blood clots in the veins, arteries and lungs • Stroke • Fits • Heart attack • Wound complications, particularly a wound that does not heal. • An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)	

Less serious side effects

Less serious side effects	What to do
Infection related: • Abscess (collection of pus, with swelling and inflammation) • Infections of the upper respiratory tract **Metabolism related:** • Decreased appetite, weight loss, altered sense of taste • Dehydration (lack of fluids) **Hormone related:** • 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) • Adrenal glands not working properly (symptoms can include weakness, tiredness, weight loss, low blood pressure) • Inflammation of the pituitary gland situated at the base of the brain (hypophysitis), swelling of the thyroid gland (thyroiditis) **Nervous system related:** • Fatigue, weakness, headache, dizziness • Numbness, tingling, burning sensation or pain in the limbs • Muscle weakness and tiredness without atrophy (myasthenic syndrome) • Decreased appetite, altered sense of taste (dysgeusia) **Ear and hearing related:** • Ringing in ears (tinnitus) **Eye and vision related:** • Dry eyes • Inflammation of the eye (which causes pain and redness) and blurred vision **Heart or circulatory system related:** • High or low blood pressure (hypertension, hypotension) **Breathing or respiratory system related:** • Shortness of breath • Cough and nose bleeding	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• Fluid around the lungs • Runny, blocked or itchy nose, sneezing (allergic rhinitis) **Gastrointestinal related:** • Stomach upset (diarrhoea, nausea, vomiting, constipation, indigestion, abdominal pain) • Redness, swelling or pain in the mouth or throat • Difficulty in speaking, hoarseness, cough • Dry mouth and pain in the mouth • Inflammation of the stomach (gastritis) • A burning or stinging sensation of the tongue • Difficulty in swallowing • Gastro-oesophageal reflux disease (bringing up stomach acid) • Inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting) • Haemorrhoids (piles) • Inflammation of the colon (colitis) • Excessive gas in the stomach or bowel (flatulence) **Liver or gallbladder related:** • Inflammation of the liver (hepatitis) • Decrease in bile flow from the liver **Skin related:** • Blisters, pain of the hands or soles of the feet, rash or redness of the skin • Dry skin, severe itching of skin, acne • Thickening of the outer layer of the skin • Skin disease with thickened patches of red skin, often with silvery scales (psoriasis) • Alopecia (hair loss and thinning), hair colour change • Hives (itchy rash) **Muscle or bone related:** • Pain in the arms, hands, legs or feet, or joints • Muscle spasms • Muscle weakness and aching muscles	

Less serious side effects	What to do
• Muscle tenderness or weakness, not caused by exercise (myopathy) • Inflammation of the joints (arthritis) and pain in joints (arthralgia) **Kidney or bladder related:** • Protein in urine (seen in tests) • Inflammation of the kidney **General:** • Pain, chills • Chest pain **Blood test related:** • Low levels of red blood cells (anaemia) • Low levels of blood platelets • Low level of or decrease in white blood cells • Low level of albumin in blood • Changes in blood tests used to monitor general health and function of your organs (including the liver and kidney), low levels of electrolytes (like magnesium, or potassium) • Increased or decreased blood glucose level • Decrease in levels of calcium, sodium and phosphate in the blood • Increase in level of potassium in the blood • Increase in the level of bilirubin in the blood (which may result in jaundice/yellow skin or eyes) • Increase in amylase levels in the blood • Increase in lipase levels in the blood • Increase in cholesterol or trygliceride levels in the blood • Increase in a type of white blood cell called eosinophils	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CABOMETYX contains

Active ingredient (main ingredient)	cabozantinib (as cabozantinib (S) -malate)
Other ingredients (inactive ingredients)	microcrystalline cellulose lactose hyprolose croscarmellose sodium colloidal anhydrous silica magnesium stearate hypromellose titanium dioxide triacetin iron oxide yellow
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

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

What CABOMETYX looks like

CABOMETYX 20 mg film-coated tablets are yellow, round with no score, and identified with "XL" on one side and "20" on the other side. (AUST R 283800)

CABOMETYX 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. (AUST R 283801)

CABOMETYX 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. (AUST R 283799)

CABOMETYX tablets are available in a plastic bottle with 30 tablets.

The bottle contains three silica gel desiccant canisters. Keep the canisters in the bottle and do not swallow the desiccant canisters.

Australian Sponsor of CABOMETYX

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