PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CABOMETYX 20 mg film-coated tablets

CABOMETYX 40 mg film-coated tablets

CABOMETYX 60 mg film-coated tablets

Cabozantinib

Contains sugar: lactose

Read all of this leaflet carefully before you start taking CABOMETYX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CABOMETYX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What CABOMETYX is and what it is used for

CABOMETYX is a cancer medicine that contains the active substance cabozantinib. CABOMETYX 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

- 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 thyroid problems. Your thyroid function should be checked before you take CABOMETYX and regularly while you are taking it. Tell your doctor if you get tired more easily, generally feel colder than other people, or your voice deepens whilst taking this medicine. If your thyroid gland is not producing enough thyroid hormone, you may be treated with thyroid hormone replacement. This medicine may also cause your thyroid gland to produce too much thyroid hormone.
- 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 CABOMETYX or stop treatment altogether. See also section 4 "Possible side effects".
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.

Children and adolescents

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

Other medicines and CABOMETYX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Please 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 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.
- 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.

Oral contraceptives

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

CABOMETYX with food and drink

You should not take CABOMETYX 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-containing products for as long as you are using this medicine, as they may increase the levels of CABOMETYX in your blood.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Avoid becoming pregnant while being treated with CABOMETYX. 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 CABOMETYX (see also under Other medicines and CABOMETYX, above).

Pregnancy: Tell your doctor if you or your partner become pregnant or plan to become pregnant while you are being treated with CABOMETYX. You should not take CABOMETYX if you are pregnant.

Talk to your doctor BEFORE taking CABOMETYX 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 CABOMETYX.

Breast-feeding: Women taking CABOMETYX 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.

Driving and using machines

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

CABOMETYX contains lactose

CABOMETYX 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.

3. How to take CABOMETYX

Do not share medicines prescribed for you with any other person.

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

CABOMETYX should be taken once a day. The usual dose is 60 mg; however, your doctor will decide on the right dose for you.

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

Your doctor will tell you how long your treatment with CABOMETYX will last. If you have the impression that the effect of CABOMETYX is too strong or too weak, tell your doctor or pharmacist.

If you take more CABOMETYX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CABOMETYX

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 taking CABOMETYX

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.

4. Possible side effects

CABOMETYX can have side effects.

Not all side effects reported for CABOMETYX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CABOMETYX, please consult your health care provider for advice.

If any of the following happens, stop taking CABOMETYX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CABOMETYX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 of the throat, or shortness of breath. These are very common (they may affect more than 1 in 10 people);
- a wound that does not heal (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), which is a temporary brain condition caused by swelling in the brain (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).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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

- Decreased amount of magnesium or potassium in the blood;
- Decreased amount of protein albumin in blood (which carries substances; such as hormones, medicines, and enzymes throughout your body);
- Bleeding;
- stomach upset, including diarrhea, nausea, vomiting, constipation, indigestion and abdominal pain;
- blisters, pain of the hands or soles of the feet, rash or redness of the skin;
- decreased appetite, weight loss, altered sense of taste;
- inflammation of the oral and gastrointestinal mucosa;
- headache, dizziness;
- feeling tired or weak;
- hypertension (increase in blood pressure);
- anemia (low levels of red blood cells which carry oxygen), low level of platelets (cells which help the blood to clot);
- redness, swelling or pain in the mouth or throat (stomatitis); Difficulty in speaking, hoarseness, cough,
- difficulty in speaking, hoarseness (dysphonia), cough and shortness of breath;
- Abnormal liver function tests (increased amounts of the liver enzymes aspartate aminotransferase, alanine aminotransferase);
- reduced thyroid activity; symptoms can include tiredness, weight gain, constipation, feeling cold and dry skin;
- swelling in your legs and arms;
- pain in the arms, hands, legs or feet;

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

- abscess (collection of pus, with swelling and inflammation);
- dehydration;
- difficulty in swallowing;
- ringing in ears (tinnitus);

- blood clots in the ~~blood vessels~~ veins and lungs;
- low level of white blood cells (which are important in fighting infection);
- high (hyperglycaemia) or low (hypoglycaemia) sugar levels in the blood;
- decrease amount of calcium, sodium and phosphate in the blood;
- increase amount of potassium in the blood;
- increase amount of the waste product of bilirubin in the blood (which may result in jaundice/yellow skin or eyes);
- increased level of the enzyme that breaks down starch (amylase);
- increased ~~in~~ level of the enzyme that breaks down fats (lipase);
- increase in cholesterol or triglyceride levels in the blood;
- Inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs);
- Inflammation of the pancreas, a painful tear or abnormal connection of the tissues in your body (fistula);
- gastro-esophageal reflux disease (bringing up stomach acid);
- hemorrhoids (piles);
- dry mouth and pain in the mouth;
- dry skin, severe itching of skin, acne, redness of the skin;
- thickening of the skin outer layer;
- alopecia (hair loss and thinning), hair color change;
- pain in joints, muscle spasms;
- protein in urine (seen in tests);
- Abnormal liver function tests (increased amounts of the liver enzymes alkaline phosphatase and gamma-glutamyl transferase in your blood);
- Abnormal kidney function tests (increased amounts of creatinine in your blood);
- 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;
- 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. Alternately you can contact Acino Pharma (Pty) Ltd via email: drugsafety_za@arceralifesciences.com

By reporting side effects, you can help provide more information on the safety of CABOMETYX.

5. How to store CABOMETYX

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CABOMETYX contains

- The active substance is cabozantinib.

  CABOMETYX 20 mg film-coated tablets:

  Each film-coated tablet contains cabozantinib (S)-malate equivalent to 20 mg cabozantinib.

  Contains sugar: lactose 15,54 mg per film-coated tablet.

  CABOMETYX 40 mg film-coated tablets:

  Each film-coated tablet contains cabozantinib (S)-malate equivalent to 40 mg cabozantinib.

  Contains sugar: lactose 31,07 mg per film-coated tablet.

  CABOMETYX 60 mg film-coated tablets:

  Each film-coated tablet contains cabozantinib (S)-malate equivalent to 60 mg cabozantinib.

  Contains sugar: lactose 46,61 mg per film-coated tablet.

- The other ingredients are:

  Tablet content:

  Anhydrous lactose, colloidal anhydrous silica, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose.

  Film-coating:

  Hypromellose 2910, iron oxide yellow (E172), titanium dioxide (E171), triacetin (E1518).

What CABOMETYX looks like and contents of the pack

CABOMETYX 20 mg film-coated tablets:
The tablets are yellow round with no score and debossed with “XL” on one side and “20” on the other side of the tablet.
CABOMETYX 40 mg film-coated tablets:

The tablets are yellow triangle shaped with no score and debossed with “XL” on one side and “40” on the other side of the tablet.

CABOMETYX 60 mg film-coated tablets:

The tablets are yellow oval shaped with no score and debossed with “XL” on one side and “60” on the other side of the tablet.

CABOMETYX film-coated tablets are packed in an HDPE bottle with a polypropylene child-resistant closure and three silica gel desiccant canisters. Each bottle contains 30 film-coated tablets.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106 16th Road

Midrand

South Africa

Tel: 087 742 1860

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CABOMETYX 20 mg – 55/26/0756

CABOMETYX 40 mg – 55/26/0757

CABOMETYX 60 mg – 55/26/0758

Access to the corresponding Professional Information

The professional information for CABOMETYX can be accessed by scanning the QR code: