

[Home](#) → [Drugs, Herbs and Supplements](#) → Cabozantinib

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Cabozantinib

pronounced as (ka" boe zan' ti nib)

Why is this medication prescribed?

Cabozantinib (Cabometyx, Cometriq) is used to treat a number of conditions.

Cabozantinib (Cabometyx) is used:

- to treat advanced renal cell carcinoma (RCC; a type of cancer that begins in the cells of the kidneys).
- in combination with nivolumab (Opdivo) to treat advanced RCC in patients who have not yet received a treatment for RCC.
- to treat hepatocellular carcinoma (HCC; a type of liver cancer) in people who were previously treated with sorafenib (Nexafar).
- to treat a certain type of thyroid cancer in adults and children 12 years of age and older that has spread to nearby tissues or to other parts of the body and that has not responded to previous a treatment and cannot be treated with radioactive iodine.

Cabozantinib (Cometriq) is used:

- to treat a certain type of thyroid cancer that is getting worse and that has spread to other parts of the body.

Cabozantinib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps slow or stop the spread of cancer cells.

How should this medicine be used?

Cabozantinib comes as a tablet (Cabometyx) and a capsule (Cometriq) to take by mouth. It is usually taken once a day on an empty stomach, at least 1 hour before and 2 hours after eating. Take cabozantinib at around the same time every day. The length of your treatment depends on how well your body responds to the medication and the side effects that you experience. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take cabozantinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets and capsules whole with a full glass (8 ounces, 240 mL) of water. Do not split, chew, crush, or open them.

Your doctor may decrease your dose of cabozantinib or permanently or temporarily stop your treatment if you experience serious side effects. Be sure to talk to your doctor about how you are feeling during your treatment with cabozantinib.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking cabozantinib,

- tell your doctor and pharmacist if you are allergic to cabozantinib (Cabometyx, Cometriq), any other medications, or any of the ingredients in cabozantinib tablets or capsules. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, you are taking or plan to take. Be sure to mention any of the following: abacavir (Ziagen, in Epzicom, in Triumeq), adefovir (Hepsera), atazanavir (Reyataz), carbamazepine (Carbatrol, Eptol, Equetro, Tegretol, Teril), cidofovir, clarithromycin (Biaxin), furosemide (Lasix), itraconazole (Sporanox, Tolsura), ketoconazole, lamivudine (Epivir, in Combivir, in Symfi, in others), nefazodone, nelfinavir (Viracept), nevirapine (Viramune), phenobarbital, phenytoin (Dilantin, Phenytek), probenecid (Probalan), rifabutin (Mycobutin), rifampin (Rifadin, Rimactane), rifapentine (Priftin), ritonavir (Norvir, in Kaletra), saquinavir (Invirase), telithromycin (Ketek), tenofovir (Viread), voriconazole (Vfend), and warfarin (Coumadin, Jantoven). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with cabozantinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have recently had any unusual or severe bleeding such as coughing up blood, vomiting blood, or bloody or black tarry stools. Also tell your doctor if you have an open or healing wound, or if you have or have ever had a low level of calcium in your blood, thyroid problems, high blood pressure, or liver disease.
- tell your doctor if you are pregnant or plan to become pregnant. You will need to have a pregnancy test before you start treatment with cabozantinib. You should not become pregnant during your treatment and for 4 months after your final dose. Talk to your doctor about birth control methods that you can use during your treatment. If you become pregnant while taking cabozantinib, call your doctor immediately. Cabozantinib may harm the fetus.
- tell your doctor if you are breastfeeding. Your doctor may tell you not to breastfeed during your treatment and for 4 months after your final dose.
- you should know that this medication may decrease fertility in men and women. Talk to your doctor about the risks of taking cabozantinib.

- if you are having surgery, tell the doctor that you are taking cabozantinib. Your doctor will probably tell you to stop taking cabozantinib at least 21 days before your surgery or procedure, and will tell you when you should start taking the medication again.
- you should know that cabozantinib may cause serious problems with your jaw. A dentist should examine your teeth before you start to take cabozantinib and regularly during your treatment. Be sure to brush your teeth and clean your mouth properly while you are taking cabozantinib. Talk to your doctor before having any dental treatments while you are taking this medication. Your doctor will probably tell you to stop taking cabozantinib at least 21 days before dental surgery.
- you should know that your blood pressure may increase during your treatment with cabozantinib. Your doctor will probably monitor your blood pressure before and during your treatment.

What special dietary instructions should I follow?

Do not drink grapefruit juice or eat grapefruit or any foods or supplements that contain grapefruit or grapefruit juice while you are taking this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is less than 12 hours until your next scheduled dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Cabozantinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- constipation
- nausea
- vomiting
- difficulty swallowing
- change in ability to taste food
- hemorrhoids
- redness, swelling, sores, or pain in your mouth or throat
- loss of appetite
- weight loss
- anxiety
- tiredness or weakness
- pale skin
- dry skin
- patchy thickening of the skin

- pain in joints, arms, or legs
- voice changes or hoarseness
- hair loss
- hair color turning lighter or gray
- slowed wound healing

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- chest pain, pressure, or tightness
- coughing up blood or blood clots
- vomiting material that is bloody or looks like coffee grounds
- menstrual bleeding that is heavier than usual
- red or black, tarry stool
- nose bleed
- diarrhea
- unusual or heavy bleeding or bruising
- tender or painful stomach area
- swelling around eyes, arms, hands, legs, feet, or ankles
- foamy urine
- shortness of breath or cough
- trouble breathing
- fast, pounding, or irregular heartbeat
- sudden severe headache
- lightheadedness or fainting
- seizures
- numbness or weakness of the face, arm, or leg on one side of your body
- sudden trouble walking
- sudden vision problems
- confusion
- sudden difficulty thinking or speaking clearly
- sudden difficulty with balance or coordination
- dizziness
- sweating more than usual

- jaw pain
- toothache
- loosening of the teeth
- swollen or painful gums
- rash
- redness, pain, swelling, or blistering on the palms or the soles
- extreme tiredness, dizziness, fainting, weakness, nausea, or vomiting
- yellowing of skin or eyes, extreme tiredness, bleeding or bruising easily, nausea or vomiting, right sided-stomach pain, dark colored urine, decreased appetite
- muscle stiffness or spasms
- sudden weight gain
- numbness, burning, or tingling in the hands, arms, feet, legs, or around the mouth

Cabozantinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- memory loss
- confusion
- weight loss

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to cabozantinib.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Cabometyx[®]
- Cometriq[®]

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