

PATIENT INFORMATION
CABOMETYX® (Ka-boe-met-iks)
cabozantinib
tablets

What is CABOMETYX?

CABOMETYX is a prescription medicine used to treat people with:

- advanced kidney cancer (renal cell carcinoma)
- liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib.

It is not known if CABOMETYX is safe and effective in children.

Before you take CABOMETYX, tell your healthcare provider about all of your medical conditions, including if you:

- have a recent history of bleeding, including coughing up or vomiting blood, or black tarry stools.
- have an open or healing wound
- have high blood pressure
- plan to have any surgery, including dental surgery. You should stop treatment with CABOMETYX at least 28 days before any scheduled surgery.
- are pregnant, or plan to become pregnant. CABOMETYX can harm your unborn baby.
 - If you are able to become pregnant, your healthcare provider will check your pregnancy status before you start treatment with CABOMETYX.
 - Females who are able to become pregnant should use effective birth control (contraception) during treatment and for 4 months after your final dose of CABOMETYX.
 - Talk to your healthcare provider about birth control methods that may be right for you.
 - If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if CABOMETYX passes into your breast milk. Do not breastfeed during treatment and for 4 months after your final dose of CABOMETYX.

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, and herbal supplements. CABOMETYX and certain other medicines may affect each other causing side effects.

How should I take CABOMETYX?

- Take CABOMETYX exactly as your healthcare provider tells you to take it.
- **Do not** take CABOMETYX with food. Take CABOMETYX at least 1 hour before or at least 2 hours after eating.
- Swallow CABOMETYX tablets whole with a full glass (at least 8 ounces) of water.
- **Do not** crush CABOMETYX tablets.
- If you miss a dose and your next dose is in:
 - less than 12 hours, take your next dose at the normal time. Do not make up the missed dose.
 - 12 hours or more, take the missed dose as soon as you remember. Take your next dose at the normal time.

What should I avoid while taking CABOMETYX?

Do not drink grapefruit juice, eat grapefruit or take supplements that contain grapefruit or St. John's wort during treatment with CABOMETYX.

What are the possible side effects of CABOMETYX?

CABOMETYX may cause serious side effects, including:

- **bleeding (hemorrhage).** CABOMETYX can cause severe bleeding that may lead to death. Tell your healthcare provider right away if you get any signs of bleeding during treatment with CABOMETYX, including:
 - coughing up blood or blood clots
 - red or black (looks like tar) stools
 - vomiting blood or if your vomit looks like
 - menstrual bleeding that is heavier than normal

<p>coffee-grounds</p> <ul style="list-style-type: none"> • a tear in your stomach or intestinal wall (perforation) or an abnormal connection between 2 parts of your body (fistula). Tell your healthcare provider right away if you get tenderness or pain in your stomach-area (abdomen). • blood clots, stroke, heart attack, and chest pain. Get emergency help right away if you get: <ul style="list-style-type: none"> ○ swelling or pain in your arms or legs ○ shortness of breath ○ feel lightheaded or faint ○ sweating more than usual ○ numbness or weakness of your face, arm or leg, especially on one side of your body • high blood pressure (hypertension). Hypertension is common with CABOMETYX and sometimes can be severe. Your healthcare provider will check your blood pressure before starting CABOMETYX and during treatment with CABOMETYX. If needed, your healthcare provider may prescribe medicine to treat your high blood pressure. • diarrhea. Diarrhea is common with CABOMETYX and can be severe. If needed, your healthcare provider may prescribe medicine to treat your diarrhea. Tell your healthcare provider right away, if you have frequent loose, watery bowel movements. • a skin problem called hand-foot skin reaction. Hand-foot skin reactions are common and can be severe. Tell your healthcare provider right away if you have rashes, redness, pain, swelling, or blisters on the palms of your hands or soles of your feet. • protein in your urine and possible kidney problems. Symptoms may include swelling in your hands, arms, legs, or feet. • severe jaw bone problems (osteonecrosis). Symptoms may include jaw pain, toothache, or sores on your gums. Your healthcare provider should examine your mouth before you start and during treatment with CABOMETYX. Tell your dentist that you are taking CABOMETYX. It is important for you to practice good mouth care during treatment with CABOMETYX. • wound healing problems. If you need to have surgery, tell your healthcare provider that you are taking CABOMETYX. Your healthcare provider should stop your treatment with CABOMETYX at least 28 days before any planned surgery, including invasive dental procedures. Your healthcare provider should tell you when you may start taking CABOMETYX again after surgery. • Reversible Posterior Leukoencephalopathy Syndrome (RPLS). A condition called reversible posterior leukoencephalopathy syndrome can happen during treatment with CABOMETYX. Tell your healthcare provider right away if you have headaches, seizures, confusion, changes in vision, or problems thinking. • CABOMETYX may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility. <p>Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with CABOMETYX if you have certain side effects.</p> <p>The most common side effects of CABOMETYX include:</p> <ul style="list-style-type: none"> • tiredness • decreased appetite • weight loss 	<ul style="list-style-type: none"> ○ any unusual or heavy bleeding ○ sudden confusion, trouble speaking or understanding ○ sudden trouble seeing in one or both eyes ○ sudden trouble walking ○ dizziness, loss of balance or coordination ○ a sudden severe headache
<p>Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of CABOMETYX. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>	
<p>How should I store CABOMETYX?</p> <ul style="list-style-type: none"> • Store CABOMETYX at room temperature 68°F to 77°F (20°C to 25°C). <p>Keep CABOMETYX and all medicines out of the reach of children.</p>	
<p>General information about the safe and effective use of CABOMETYX.</p> <p>Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use CABOMETYX for a condition for which it was not prescribed. Do not give CABOMETYX to</p>	

other people, even if they have the same symptoms you have. It may harm them.
You can ask your healthcare provider or pharmacist for information about CABOMETYX that is written for health professionals.

What are the ingredients in CABOMETYX?

Active ingredient: cabozantinib

Inactive ingredients: microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide, and magnesium stearate. The film coating contains hypromellose, titanium dioxide, triacetin, and iron oxide yellow.

Manufactured for Exelixis, Inc. Alameda, CA 94502

For more information, go to www.cabometryx.com or call 1-855-292-3935.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 01/2019