

PATIENT INFORMATION
COMETRIQ® (Ko-me-trik)
cabozantinib
capsules

What is the most important information I should know about COMETRIQ?

COMETRIQ can cause serious side effects which can lead to death, including:

- **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:
 - severe pain in your stomach-area (abdomen)
 - coughing, gagging, and choking especially when eating or drinking
- **Severe bleeding (hemorrhage).** Tell your healthcare provider right away if you get any signs of bleeding while taking or after you stop taking COMETRIQ, including:
 - coughing up blood or blood clots
 - vomiting blood or if your vomit looks like coffee-grounds
 - red or black (looks like tar) stools
 - menstrual bleeding that is heavier than normal
 - any unusual or heavy bleeding

What is COMETRIQ?

COMETRIQ is a prescription medicine used to treat people with medullary thyroid cancer that has spread to other parts of the body.

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

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

- have a recent history of coughing up blood or bleeding or any unusual bleeding
- have an open wound
- have high blood pressure
- plan to have any surgery or a dental procedure
- have liver problems
- are pregnant or plan to become pregnant. COMETRIQ can harm your unborn baby. If you are able to become pregnant, you should use effective birth control during treatment and for 4 months after the final dose of COMETRIQ. 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 COMETRIQ passes into your breast milk. Do not breastfeed during treatment and for 4 months after the final dose of COMETRIQ.

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

How should I take COMETRIQ?

- Take COMETRIQ exactly as your healthcare provider tells you to take it.
- **Do not** take COMETRIQ with food. **Do not** eat for at least 2 hours before and at least 1 hour after taking COMETRIQ.
- Swallow COMETRIQ capsules whole with a full glass (at least 8 ounces) of water.
- Do not crush or open COMETRIQ capsules.
- 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 COMETRIQ?

Do not drink grapefruit juice, eat grapefruit or supplements that contain grapefruit during treatment with COMETRIQ.

What are the possible side effects of COMETRIQ?

COMETRIQ may cause serious side effects, including:

- See “**What is the most important information I should know about COMETRIQ?**”
- **blood clots, stroke, heart attack, and chest pain.** Get emergency help right away if you get:
 - 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
 - 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
- **wound healing problems.** If you need to have surgery, tell your healthcare provider that you are taking COMETRIQ. Your healthcare provider should stop your treatment with COMETRIQ at least 28 days before any planned surgery, including dental procedures. Your healthcare provider should tell you when you may start taking COMETRIQ again after surgery.
- **high blood pressure (hypertension).** Hypertension is common with COMETRIQ and can be severe. Your healthcare provider will check your blood pressure before starting COMETRIQ and during treatment with COMETRIQ. If needed, your healthcare provider may prescribe medicine to treat your high blood pressure.
- **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 COMETRIQ. Tell your dentist that you are taking COMETRIQ. It is important for you to practice good mouth care during treatment with COMETRIQ.
- **a skin problem called hand-foot skin reaction.** Hand-foot skin reactions are common with COMETRIQ 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.
- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** A condition called reversible posterior leukoencephalopathy syndrome can happen during treatment with COMETRIQ. Tell your healthcare provider right away if you have headaches, seizures, confusion, changes in vision, or problems thinking.

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with COMETRIQ if you have certain side effects.

The most common side effects of COMETRIQ are:

- diarrhea
- redness, swelling or pain in your mouth or throat, or mouth sores. Tell your healthcare provider if these symptoms prevent you from eating or drinking.
- weight loss
- decreased appetite
- nausea
- tiredness
- hair color turning lighter
- change in taste
- pain in your abdomen
- constipation
- increased liver function blood tests
- decreased calcium and phosphate blood levels
- decreased white blood cell counts
- decreased platelet counts
- increased bilirubin blood levels

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of COMETRIQ. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store COMETRIQ?

- Store COMETRIQ at room temperature 68°F to 77°F (20°C to 25°C).

Keep COMETRIQ and all medicines out of the reach of children.

General information about COMETRIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use COMETRIQ for a condition for which it was not prescribed. Do not give COMETRIQ to 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 COMETRIQ that is written for health professionals.

What are the ingredients in COMETRIQ?

Active ingredient: cabozantinib

Inactive ingredients: silicified microcrystalline cellulose, croscarmellose sodium, sodium starch glycolate, fumed silica, and stearic acid

Capsule shells: Grey gelatin capsule shells contain black iron oxide and titanium dioxide. Swedish orange gelatin capsule shells contain red iron oxide, and titanium dioxide.

The printing ink contains shellac glaze, black iron oxide, N-butyl alcohol, isopropyl alcohol, propylene glycol, and ammonium hydroxide.

Manufactured for Exelixis, Inc. South San Francisco, CA 94080

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

This Patient Information has been approved by the U.S. Food and Drug Administration.

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