Accessing COMETRIQ® (cabozantinib) Capsules

Specialty Pharmacies and Distributors

Contact one of these authorized in-network specialty pharmacies or distributors for access to COMETRIQ.

Specialty Pharmacies (US)	Phone	Fax	Website
Accredo Specialty Pharmacy	1-877-732-3431	1-866-352-3973	accredo.com
BioPlus Specialty Pharmacy	1-833-662-3279	1-800-269-5493	bioplusrx.com
CVS Caremark Specialty Pharmacy	1-877-233-9920	1-855-296-0210	cvsspecialty.com
Optum Specialty Pharmacy	1-855-427-4682	1-877-342-4596	specialty.optumrx.com

340B, VA and NCI/NCCN Cancer Centers	Phone	Fax/Email	Website
Cardinal Health Specialty Distribution*	1-855-855-0708	1-614-553-6301	specialtyonline.cardinalhealth.com orderexpress.cardinalhealth.com
McKesson Plasma and Biologics	1-877-625-2566	1-888-752-7626	connect.mckesson.com

*NCCN Comprehensive Cancer Center members only.

EASE EXELIXIS ACCESS SERVICES®

Exelixis Access Services® (EASE) is your resource for questions and needs related to financial assistance for COMETRIQ.

CALL: 1-844-900-EASE
(1-844-900-3273)

Monday to Friday
8:00 AM to 8:00 PM (ET)

For more information about accessing COMETRIQ, visit www.cometriq.com/hcp/access/.

Please see Important Safety Information on pages 2-3 and full Prescribing Information for COMETRIQ.

COMETRIQ® (cabozantinib) 80 mg and 20 mg capsules

INDICATION

COMETRIQ® (cabozantinib) is indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Perforations and Fistulas: Gastrointestinal (GI) perforations and fistulas, including fatal cases, and non-GI fistulas, including tracheal/esophageal fistulas, including fatal cases, were reported in COMETRIQ-treated patients. Monitor patients for symptoms of perforations and fistulas, including abscess and sepsis. Discontinue COMETRIQ in patients who experience a Grade 4 fistula or a GI perforation.

Hemorrhage: Severe and fatal hemorrhage occurred with COMETRIQ. The incidence of Grade ≥3 hemorrhagic events was higher in COMETRIQ-treated patients compared with placebo. Discontinue COMETRIQ for Grade 3 or 4 hemorrhage. Do not administer COMETRIQ to patients with a recent history of hemorrhage, including hemoptysis, hematemesis, or melena.

Thromboembolic Events: COMETRIQ treatment resulted in an increased incidence of venous thromboembolism and arterial thromboembolism. Discontinue COMETRIQ in patients who develop an acute myocardial infarction or arterial or venous thromboembolic events that require medical intervention.

Impaired Wound Healing: Wound complications have been reported with COMETRIQ. Withhold COMETRIQ for at least 3 weeks prior to elective surgery. Do not administer COMETRIQ for at least 2 weeks after major surgery and until adequate wound healing is observed. The safety of resumption of COMETRIQ after resolution of wound healing complications has not been established.

Hypertension and Hypertensive Crisis: COMETRIQ treatment resulted in an increased incidence of treatment-emergent hypertension. Do not initiate COMETRIQ in patients with uncontrolled hypertension. Monitor blood pressure regularly and withhold COMETRIQ for hypertension that is not adequately controlled with medical management; when controlled, resume COMETRIQ at a reduced dose. Discontinue COMETRIQ for severe hypertension that cannot be controlled with anti-hypertensive therapy and for hypertensive crisis.

Cardiac Failure: COMETRIQ can cause severe and fatal cardiac failure. Cardiac failure occurred in 0.9% of patients treated with COMETRIQ as a single agent. Consider baseline and periodic evaluations of left ventricular ejection fraction. Monitor for signs and symptoms of cardiovascular events. Withhold and resume at a reduced dose upon recovery or permanently discontinue depending on the severity.

Osteonecrosis of the Jaw (ONJ): ONJ can manifest as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration or erosion, or persistent jaw pain or slow healing of the mouth or jaw after dental surgery. Perform an oral examination prior to initiation of COMETRIQ and periodically during COMETRIQ treatment. Advise patients regarding good oral hygiene practices. Withhold COMETRIQ treatment for at least 3 weeks prior to scheduled dental surgery or invasive dental procedures, if possible. Withhold COMETRIQ for development of ONJ until complete resolution.

Diarrhea: Grade 3 to 4 diarrhea occurred in patients treated with COMETRIQ. Withhold COMETRIQ until improvement to Grade 1 and resume COMETRIQ at a reduced dose for intolerable Grade 2 diarrhea, Grade 3 diarrhea that cannot be managed with standard antidiarrheal treatments, or Grade 4 diarrhea.

Palmar-Plantar Erythrodysesthesia (PPE): PPE, sometimes severe (Grade 3), occurred in patients treated with COMETRIQ. Withhold COMETRIQ in patients who develop intolerable Grade 2 PPE or Grade 3 PPE until improvement to Grade 1; resume COMETRIQ at a reduced dose.

Proteinuria: Monitor urine protein regularly during COMETRIQ treatment. Discontinue COMETRIQ in patients who develop nephrotic syndrome.

Please see additional Important Safety Information on page 3 and full Prescribing Information for COMETRIQ.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS occurred in 1 (<1%) Cabometyx patient. Evaluate for RPLS in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue COMETRIQ in patients who develop RPLS.

Embryo-Fetal Toxicity: COMETRIQ can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during COMETRIQ treatment and for 4 months after the last dose.

Hypocalcemia: COMETRIQ can cause hypocalcemia, including Grade 3 or 4. Monitor blood calcium levels and replace calcium as necessary during treatment. Withhold and resume at a reduced dose upon recovery or discontinue COMETRIQ depending on severity.

ADVERSE REACTIONS

The most commonly reported adverse drug reactions (≥25% and ≥5% difference vs placebo) were: diarrhea, stomatitis, PPE, decreased weight), decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain, and constipation.

The most common laboratory abnormalities (≥25%) were increased AST, increased ALT, lymphopenia, increased ALP, hypocalcemia, hypoalbuminemia, neutropenia, thrombocytopenia, hypophosphatemia, and hyperbilirubinemia.

DRUG INTERACTIONS

Strong CYP3A4 Inhibitors: Reduce the dosage of COMETRIQ if concomitant use with strong CYP3A4 inhibitors cannot be avoided. Avoid grapefruit or grapefruit juice.

Strong CYP3A4 Inducers: Increase the dosage of COMETRIQ if concomitant use with strong CYP3A4 inducers cannot be avoided. Avoid St. John's wort.

USE IN SPECIFIC POPULATIONS

Lactation: Advise lactating women not to breastfeed during treatment with COMETRIQ and for 4 months after the final dose.

Reproductive Potential: Verify the pregnancy status of females of reproductive potential before starting treatment with COMETRIQ. COMETRIQ may impair fertility in females and males of reproductive potential.

Hepatic Impairment: Reduce the COMETRIQ dosage in patients with mild to moderate hepatic impairment. COMETRIQ is not recommended for use in patients with severe hepatic impairment.

Please see additional Important Safety Information on page 2 and full Prescribing Information for COMETRIQ.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.