

CABOMETYX[®]: Treatment of Patients with Advanced Renal Cell Carcinoma

15th Annual Miami Cancer Meeting

Presented by:
Shilpa Gupta, MD
University of Minnesota - Cancer Center

Date: Saturday, April 28, 2018

Time: 12:25pm

Location: Conrad

1395 Brickell Ave.
Miami, FL 33131

Hosted by: Rosie Gonzalez

rgonzalez@exelixis.com
305-992-5799

Register for this program today!*

Indication:

CABOMETYX[®] is indicated for the treatment of patients with advanced renal cell carcinoma (RCC).

Please see Important Safety Information on the following page and full Prescribing Information at this presentation and at <https://www.cabometryx.com/downloads/CABOMETRYXUSPI.pdf>.

Contact your local sales representative if you have any questions regarding this program.

Registration:

1. RSVP to
Rosie Gonzalez
rgonzalez@exelixis.com
305-992-5799
2. Or Register Online at <http://bit.ly/2FRKeV5>
3. Or you may complete the registration form below and fax it to 888-269-4201

Full Name	Credentials	Title	
Institution	City	State	Zip Code
Email Address	Phone		
License Number (only if licensed in MA or MN)	788 Meeting Code		

*Program is intended for HCPs including: Oncologists, NPs, PAs, RNs, Pharmacists, Medical Assistants

Important Safety Information

WARNINGS AND PRECAUTIONS

Hemorrhage: Severe and fatal hemorrhages have occurred with CABOMETYX. In RCC trials, the incidence of Grade ≥ 3 hemorrhagic events was 3% in CABOMETYX patients. Do not administer CABOMETYX to patients that have or are at risk for severe hemorrhage.

Gastrointestinal (GI) Perforations and Fistulas: In RCC trials, GI perforations were reported in 1% of CABOMETYX patients. Fatal perforations occurred in patients treated with CABOMETYX. In RCC studies, fistulas were reported in 1% of CABOMETYX patients. Monitor patients for symptoms of perforations and fistulas, including abscess and sepsis. Discontinue CABOMETYX in patients who experience a GI perforation or a fistula that cannot be appropriately managed.

Thrombotic Events: Thrombotic events increased with CABOMETYX. In RCC trials, venous thromboembolism occurred in 9% (including 5% pulmonary embolism) and arterial thromboembolism occurred in 1% of CABOMETYX patients. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETYX in patients who develop an acute myocardial infarction or any other arterial thromboembolic complication.

Hypertension and Hypertensive Crisis: Treatment-emergent hypertension, including hypertensive crisis, increased with CABOMETYX. In RCC trials, hypertension was reported in 44% (18% Grade ≥ 3) of CABOMETYX patients. Monitor blood pressure prior to initiation and regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX if there is evidence of hypertensive crisis or for severe hypertension that cannot be controlled with antihypertensive therapy or medical management.

Diarrhea: In RCC trials, diarrhea occurred in 74% of CABOMETYX patients. Grade 3 diarrhea occurred in 11% of CABOMETYX patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 diarrhea or Grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to Grade 1; resume CABOMETYX at a reduced dose.

Palmar-Plantar Erythrodysesthesia (PPE): In RCC trials, PPE occurred in 42% of CABOMETYX patients. Grade 3 PPE occurred in 8% of CABOMETYX patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 PPE or Grade 3 PPE until improvement to Grade 1; resume CABOMETYX at a reduced dose.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Evaluate for RPLS in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

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

ADVERSE REACTIONS

The most commonly reported ($\geq 25\%$) adverse reactions were: diarrhea, fatigue, nausea, decreased appetite, hypertension, PPE, weight decreased, vomiting, dysgeusia, and stomatitis.

DRUG INTERACTIONS

Strong CYP3A4 Inhibitors: If concomitant use with strong CYP3A4 inhibitors cannot be avoided, reduce the CABOMETYX dosage.

Strong CYP3A4 Inducers: If concomitant use with strong CYP3A4 inducers cannot be avoided, increase the CABOMETYX dosage.

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed while taking CABOMETYX and for 4 months after the final dose.

Hepatic Impairment: In patients with mild to moderate hepatic impairment, reduce the CABOMETYX dosage. CABOMETYX is not recommended for use in patients with severe hepatic impairment.

Please see accompanying full Prescribing Information at <https://www.cabometryx.com/downloads/CABOMETYXUSPI.pdf>.

Minnesota, Vermont, the Department of Defense, and the Department of Veterans Affairs, and certain institutions have restrictions on receiving in-kind benefits (e.g., meals, valet parking) at company-sponsored events. You are accountable for understanding and complying with such restrictions. If you are licensed in or affiliated with any of these states, federal agencies, or institutions, Exelixis policies may restrict you from consuming any portion of the Exelixis-sponsored meal at this program or from receiving any other in-kind benefit from Exelixis (e.g., valet parking) in connection with the program.

For all program attendees who receive in-kind benefits at this program, Exelixis will report the attendee's name and the value received as required by federal and state disclosure laws.

The meal cost may vary by event location and be up to \$135 per person (exceptions may apply).

Please refrain from inviting guests or spouses to these educational programs. Non-healthcare professionals are strictly prohibited from attending such programs.

This program is not certified for Continuing Medical Education credit.