

Prescribing CAPRELSA

Important Safety Information
Including Boxed WARNING

Approved Indication

Full Prescribing Information
for CAPRELSA 

Medication Guide
for CAPRELSA 

CAPRELSA Prescription
Form 

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Welcome to the CAPRELSA REMS Program

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CAPRELSA® (vandetanib) Tablets, a kinase inhibitor, is approved by the Food and Drug Administration (FDA) for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Use CAPRELSA in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of CAPRELSA.

CAPRELSA can prolong the QT interval and cases of Torsades de pointes and sudden death have occurred in patients receiving CAPRELSA. Because of this risk, CAPRELSA is only available through the CAPRELSA Risk Evaluation and Mitigation Strategy (REMS) Program. [Read more.](#)

The CAPRELSA REMS Program has the following specific goals:

- To educate prescribers about the risk, appropriate monitoring, and management of QT prolongation to help minimize the occurrence of Torsades de pointes and sudden death
- To inform patients about the serious risks associated with CAPRELSA

Under the CAPRELSA REMS Program, only certified prescribers can prescribe CAPRELSA.

CAPRELSA REMS Program: Learn and Enroll

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INDICATIONS AND USAGE

CAPRELSA is a kinase inhibitor indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

Use CAPRELSA in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of CAPRELSA.

Important Safety Information, including Boxed WARNING, for CAPRELSA

WARNING: QT PROLONGATION, TORSADES DE POINTES, AND SUDDEN DEATH

- CAPRELSA can prolong the QT interval. Torsades de pointes and sudden death have occurred in patients receiving CAPRELSA
- Do not use CAPRELSA in patients with hypocalcemia, hypokalemia, hypomagnesemia, or long QT syndrome. Correct hypocalcemia, hypokalemia and/or hypomagnesemia prior to CAPRELSA administration
- Monitor electrolytes periodically
- Avoid drugs known to prolong the QT interval
- Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense CAPRELSA

- Do not use in patients with congenital long QT syndrome
- CAPRELSA can prolong the QT interval in a concentration-dependent manner. Torsades de pointes, ventricular tachycardia and sudden deaths have occurred in patients treated with CAPRELSA
- Do not start CAPRELSA treatment in patients whose QTcF interval (corrected QT interval, Fridericia) is greater than 450 ms or who have a history of Torsades de pointes, bradyarrhythmias, or uncompensated heart failure. CAPRELSA has not been studied in patients with ventricular arrhythmias or recent myocardial infarction
- Stop CAPRELSA in patients who develop a QTcF greater than 500 ms until QTcF returns to less than 450 ms. Dosing of CAPRELSA can then be resumed at a reduced dose
- Because of the risk of QT prolongation, obtain an ECG and serum potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH) at baseline, 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA, and every 3 months thereafter. Following any dose reduction or interruptions greater than 2 weeks, conduct QT assessments as described above
- Severe skin reactions (including Stevens-Johnson syndrome), some leading to death, have occurred in patients treated with CAPRELSA. Consider permanent discontinuation of CAPRELSA for severe skin reactions
- Photosensitivity reactions can occur during CAPRELSA treatment and up to 4 months after treatment discontinuation
- Interstitial lung disease (ILD) or pneumonitis, including fatalities, has occurred in patients treated with CAPRELSA. Interrupt CAPRELSA for acute or worsening pulmonary symptoms and discontinue CAPRELSA if ILD is confirmed
- Ischemic cerebrovascular events, including fatalities, occurred in patients treated with CAPRELSA. The safety of resumption of CAPRELSA therapy after resolution of an ischemic cerebrovascular event has not been studied. Discontinue CAPRELSA in patients who experience a severe ischemic cerebrovascular event
- Serious hemorrhagic events, including fatalities, occurred in patients treated with CAPRELSA. Do not administer CAPRELSA to patients with a recent history of hemoptysis of $\geq 1/2$ teaspoon of red blood. Discontinue CAPRELSA in patients with severe hemorrhage
- Heart failure, including fatalities, occurred in patients treated with CAPRELSA. Monitor for signs and symptoms of heart failure. Consider discontinuation of CAPRELSA in patients with heart failure. Heart failure may not be reversible upon stopping CAPRELSA
- Diarrhea of Grade 3 or greater severity occurred in patients receiving CAPRELSA. If diarrhea occurs, carefully monitor serum electrolytes and ECGs to enable early detection of QT prolongation resulting from dehydration. Interrupt CAPRELSA for severe diarrhea and upon improvement resume CAPRELSA at a reduced dose
- Increased dosing of thyroid replacement therapy was required in 49% of CAPRELSA-treated patients. Obtain TSH at baseline, at 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA, and every 3 months thereafter. If signs or symptoms of hypothyroidism occur, examine thyroid hormone levels and adjust thyroid replacement therapy accordingly
- Hypertension, including hypertensive crisis, has occurred in patients treated with CAPRELSA. Monitor all patients for hypertension. Dose reduction or interruption for hypertension may be necessary. If hypertension cannot be controlled, do not resume CAPRELSA
- Reversible posterior leukoencephalopathy syndrome (RPLS) has occurred in patients treated with CAPRELSA. Consider this syndrome in any patient presenting with seizures, headache, visual disturbances, confusion or altered mental function. In clinical studies, three of four patients who developed RPLS while taking CAPRELSA also had hypertension. Discontinue CAPRELSA treatment in patients with RPLS
- Avoid administration of CAPRELSA with anti-arrhythmic drugs and other drugs that may prolong the QT interval
- Vandetanib exposure is increased in patients with impaired renal function. Reduce the starting dose to 200 mg in patients with moderate to severe renal impairment and monitor the QT interval closely. There is no information available for patients with end-stage renal disease requiring dialysis
- CAPRELSA is not recommended for patients with moderate and severe hepatic impairment, as safety and efficacy have not been established
- CAPRELSA can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should avoid pregnancy and be advised that they must use effective contraception during CAPRELSA treatment and for at least 4 months following the last dose of CAPRELSA
- The most commonly reported adverse drug reactions ($>20\%$) seen with CAPRELSA and with a between-arm difference of $\geq 5\%$ are diarrhea/colitis (57%), rash (53%), acneiform dermatitis (35%), hypertension (33%), nausea (33%), headache (26%), upper respiratory tract infections (23%), decreased appetite (21%), and abdominal pain (21%)
- CAPRELSA REMS Program: Because of the risks of QT prolongation, Torsades de pointes, and sudden death, CAPRELSA is available only through the CAPRELSA REMS Program. Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense CAPRELSA. To learn about the specific REMS requirements and to enroll in the CAPRELSA REMS Program, call 1-800-236-9933 or visit www.caprelsarems.com

Please see the [full Prescribing Information for CAPRELSA, including boxed WARNING.](#) 

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.

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[Enroll](#) in the CAPRELSA REMS Program to become certified to prescribe.

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