



REMS PROGRAM
RISK EVALUATION AND MITIGATION STRATEGY

Important Information for Healthcare Providers About the Risk of QT Prolongation, Torsades de Pointes, and Sudden Death With CAPRELSA (vandetanib) Tablets

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, a restricted distribution program. Under the CAPRELSA REMS Program, **only prescribers and pharmacies certified with the program are able to prescribe and dispense CAPRELSA.**

In order to prescribe CAPRELSA, a physician must:

- Review the educational materials, including:
 - Risk information regarding QT prolongation, Torsades de pointes, and sudden death with CAPRELSA
 - Considerations for patient selection
 - ECG and electrolyte monitoring requirements
 - Drug interaction information
 - Dosage and administration information
- Complete the Prescriber Training Program
- Complete the Prescriber Enrollment Form

CAPRELSA is a kinase inhibitor that has been approved by the United States Food and Drug Administration for:

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.

To learn more about the specific REMS requirements and to ENROLL in the CAPRELSA REMS Program call 1-800-236-9933 or visit www.caprelsarems.com

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