

Appendix 4 *CAPRELSA REMS Prescriber Enrollment Screenshot*

New Prescriber Enrollment Form

* First Name Middle Initial * Last Name

* Credentials MD DO NP PA Other

* Physician Specialty Medical Oncologist Endocrinologist Surgeon Other

* Name of Facility

* Address 1

Address 2

* City * State * Zip Code

* Phone Number Fax Number

* Email

* State License Number * State of Issue

* National Provider Identification (NPI) Number

[Prescriber Training Program Questions](#)

Prescriber Agreement

Prescriber Agreement

I understand that CAPRELSA is only available through the CAPRELSA REMS Program and I must comply with the program requirements. In addition, I acknowledge that:

1. I have read the CAPRELSA REMS Prescriber Training Pamphlet or the CAPRELSA REMS Prescriber Training Slide Deck, and the Prescribing Information for CAPRELSA, and I have completed the CAPRELSA REMS Prescriber Training Questions.
2. I understand that 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.
3. **Risk of QT prolongation, Torsades de pointes, and Sudden Death**
 - a. I understand that CAPRELSA can prolong the QT interval in a concentration- dependent manner, and that Torsades de pointes, ventricular tachycardia and sudden deaths have occurred in patients receiving CAPRELSA.
 - b. I understand that a prolonged QT interval may NOT resolve quickly because of the 19- day half-life.
 - c. I understand that CAPRELSA® (vandetanib) Tablets must not be administered to patients with congenital long QT syndrome.
 - d. I will report cases of QT prolongation, Torsades de pointes, and sudden death to Sanofi Genzyme.
4. **QT Monitoring – I understand that**
 - a. ECGs should be obtained to monitor the QT at **baseline, at 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA and every 3 months thereafter.**
 - b. Patients who develop a QTcF greater than 500 ms should stop taking CAPRELSA until QTcF returns to less than 450 ms. Dosing of CAPRELSA can then be resumed at a reduced dose.
 - c. Following any dose reduction for QT prolongation, or any dose interruptions greater than 2 weeks, QT assessment should be conducted as described above.
5. **Electrolyte Monitoring – I understand that**
 - a. CAPRELSA should not be used in patients with hypocalcemia, hypokalemia, and/or hypomagnesemia.
 - b. Hypocalcemia, hypokalemia and/or hypomagnesemia must be corrected prior to CAPRELSA administration and should be periodically monitored.
 - c. Electrolytes may require more frequent monitoring in patients who experience diarrhea.
6. **Drug Interactions – I understand that**
 - a. Drugs known to prolong the QT interval should be avoided.

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- b. If drugs known to prolong the QT interval are given to patients already receiving CAPRELSA and no alternative therapy exists, I need to perform ECG monitoring of the QT interval more frequently.

7. Dosing – I understand

- a. Vandetanib exposure is increased in patients with impaired renal function. The starting dose should be reduced to 200 mg in patients with moderate to severe renal impairment and QT interval should be monitored closely.
 - b. How to properly dose and administer CAPRELSA.
- 8. I will review and counsel each patient or caregiver on the CAPRELSA Patient Brochure and the risks and benefits of CAPRELSA.
 - 9. I understand that CAPRELSA will only be available through pharmacies certified with the CAPRELSA REMS Program.
 - 10. I understand that CAPRELSA is only available through the CAPRELSA REMS Program. I understand and agree to comply with the CAPRELSA REMS Program requirements for prescribers.

*

I Agree I do not agree (are you certain you wish to select disagree? By not agreeing to the prescriber agreement statements you will not be able to prescribe CAPRELSA. Click ok to continue or cancel to change your selection).

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