

The CAPRELSA REMS Program Prescriber Enrollment Form

A prescriber must enroll in the CAPRELSA REMS Program to prescribe CAPRELSA[®] (vandetanib) Tablets. Please complete the information below and then continue with certification by clicking the NEXT button on your screen

Prescriber Information

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 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 HCP Educational Pamphlet or the HCP REMS Education Slide Set, and the Full Prescribing Information for CAPRELSA, including the Medication Guide, and I have completed the prescriber training program.
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.

If you have any enrollment questions, please call (1-800-236-9933)
Please visit www.caprelsarems.com for more information

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- c. I understand that CAPRELSA[®] (vandetanib) Tablets must not be administered to patients with congenital long QT syndrome, a history of uncompensated heart failure, bradyarrhythmias, and Torsades de pointes.
 - d. I will report cases of Torsades de pointes and sudden death to AstraZeneca.
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.
 - 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 Medication Guide 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.

Prescriber Signature: _____ Date: _____

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