Appendix 7   CAPRELSA REMS Program Website Screenshots
Welcome to the CAPRELSA REMS Program

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 goals of the CAPRELSA REMS Program are to mitigate the serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of CAPRELSA by:

- Educating prescribers on the following:
  - Serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of CAPRELSA
  - The need to monitor for QT prolongation and electrolyte abnormalities
  - Appropriate management of QT prolongation to minimize the occurrence of Torsades de pointes and sudden death associated with use of CAPRELSA

- Informing patients on the following:
  - Serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of CAPRELSA

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

Please see the Prescribing Information for CAPRELSA, including boxed WARNING.

Only certified prescribers can prescribe CAPRELSA.
Enroll in the CAPRELSA REMS Program to become certified to prescribe.

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.

CAPRELSA is a registered trademark of Genzyme Corporation.

Privacy Notice | Legal Terms and Conditions | Site Map | Contact Us

US Corporate Site | Prescribing Information

This product information is intended for US healthcare professionals only.

©2016 Genzyme Corporation, All rights reserved. Last Updated July 2016.
Educational Materials for Healthcare Providers

The CAPRELSA® (vandetanib) Tablets REMS Program provides important information on the risks associated with CAPRELSA as well as information on recommended monitoring and management of patients receiving CAPRELSA.

In order to become a certified prescriber, you must review the following educational materials:

CAPRELSA REMS Prescribing Training Pamphlet, or CAPRELSA REMS Prescribing Training Slide Deck, and CAPRELSA Prescribing Information.

Please see the Prescribing Information for CAPRELSA, including boxed WARNING.

Only certified prescribers can prescribe CAPRELSA.
Enroll in the CAPRELSA REMS Program to become certified to prescribe.

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.

CAPRELSA is a registered trademark of Genzyme Corporation.

Privacy Notice | Legal Terms and Conditions | Site Map | Contact Us

US Corporate Site | Prescribing Information

This product information is intended for US healthcare professionals only.

©2016 Genzyme Corporation, All rights reserved. Last Updated July 2016.
Learn About the CAPRELSA REMS Program

To prescribe CAPRELSA® (vandetanib) Tablets, you must enroll in the CAPRELSA REMS Program and complete the prescriber training program.

Certification in the CAPRELSA REMS Program requires 4 steps:

1. Review CAPRELSA REMS Prescribing Training Pamphlet, or CAPRELSA REMS Prescribing Training Slide Deck, and the CAPRELSA Prescribing Information.

2. Begin enrollment in the CAPRELSA REMS Program by filling out the demographic information in the CAPRELSA REMS Prescriber Enrollment Form online or by calling the CAPRELSA REMS Program.

3. Continue with the enrollment process by completing the CAPRELSA REMS Prescriber Training Questions online or by calling the CAPRELSA REMS Program.

4. Complete the enrollment process by reviewing and acknowledging the prescriber agreement, including acknowledgement to review the CAPRELSA Patient Brochure with the patient or caregiver online or by calling the CAPRELSA REMS Program. At the completion of this process the prescriber is enrolled in the REMS and is considered certified to prescribe CAPRELSA.

Enroll online or call 1-800-017-2722.

Distribution of CAPRELSA

CAPRELSA is not available at retail pharmacies and can only be dispensed through a restricted distribution program.

Please see the Prescribing Information for CAPRELSA, including boxed WARNING.

Only certified prescribers can prescribe CAPRELSA. Enroll in the CAPRELSA REMS Program to become certified to prescribe.

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.

CAPRELSA is a registered trademark of Genzyme Corporation.
Welcome to the CAPRELSA® (vandetanib) REMS Program

**Prescribers**

- New Enrollment
- Resume Enrollment

**Pharmacies**

- Verify Prescriber Enrollment
Contact Us

If you would like additional information regarding the CAPRELSA REMS Program, please contact Sanofi Genzyme at 1-800-745-4447, Monday through Friday, 8:00 AM to 6:00 PM ET.

Please see the Prescribing Information for CAPRELSA, including boxed WARNING.

Only certified prescribers can prescribe CAPRELSA.
Enroll in the CAPRELSA REMS Program to become certified to prescribe.

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.

CAPRELSA is a registered trademark of Genzyme Corporation.
Site Map

- REMS Home
- Educational Materials
- Learn About the CAPRELSA REMS Program
- Contact Us

Please see the Prescribing Information for CAPRELSA, including boxed WARNING.

Only certified prescribers can prescribe CAPRELSA. Enroll in the CAPRELSA REMS Program to become certified to prescribe.

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.

CAPRELSA is a registered trademark of Genzyme Corporation.

Privacy Notice | Legal Terms and Conditions | Site Map | Contact Us

US Corporate Site | Prescribing Information

This product information is intended for US healthcare professionals only.

©2016 Genzyme Corporation, All rights reserved. Last Updated July 2016.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFERY L SUMMERS
05/16/2017