

Most recent modification: May 2017

Initial REMS Approval: 04/2011

NDA 22-405 CAPRELSA[®] (vandetanib)

Kinase inhibitor

Genzyme Corporation

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Cambridge, MA 02142

1-800-817-2722

RISK EVALUATION AND MITIGATION STRATEGY

I. GOALS

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.

II. ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe CAPRELSA are specially certified.

- a. Genzyme Corporation (Genzyme) must ensure that healthcare providers who prescribe CAPRELSA are specially certified.
- b. To become certified to prescribe CAPRELSA, healthcare providers must:

- 1) Review the *CAPRELSA REMS Prescriber Training Pamphlet* or *CAPRELSA REMS Prescriber Training Slide Deck* and the Prescribing Information.
- 2) Complete the *CAPRELSA REMS Prescriber Training Questions* and submit the responses to these questions online or by telephone to the CAPRELSA REMS Program at 1-800-817-2722.
- 3) Enroll in the CAPRELSA REMS Program by completing the *CAPRELSA REMS Prescriber Enrollment Form* online or by telephone.
- 4) Agree to review the *CAPRELSA Patient Brochure* with the patient or caregiver.

Genzyme must:

- 1) Ensure that prescriber enrollment can successfully be completed via the CAPRELSA REMS website, or by telephone via the CAPRELSA Program Coordinating Call Center at 1-800-817-2722. The CAPRELSA REMS website (www.caprelsarems.com) is part of the CAPRELSA REMS Program and is appended.
- 2) Ensure that, as part of the enrollment process, prescribers receive or have access to the following materials that are part of the CAPRELSA REMS Program and are appended:

CAPRELSA REMS Prescriber Training Pamphlet
CAPRELSA REMS Prescriber Training Slide Deck
CAPRELSA REMS Prescriber Training Questions
CAPRELSA REMS Prescriber Enrollment Form
CAPRELSA Patient Brochure

- 3) Ensure that prescribers have completed the training and ensure that the enrollment form is complete before activating a prescriber's enrollment in the CAPRELSA REMS Program.
- 4) Ensure that prescribers are notified when they are successfully enrolled in the CAPRELSA REMS Program, and therefore, are certified to prescribe CAPRELSA.

2. CAPRELSA must only be dispensed by pharmacies that are specially certified.

- a. Genzyme must ensure that CAPRELSA will only be dispensed by certified pharmacies. To become certified to dispense CAPRELSA, each pharmacy must be enrolled in the CAPRELSA REMS Program.
- b. To become certified, the authorized pharmacist on behalf of the pharmacy must agree to the following:
 - 1) I understand that only prescribers enrolled in the CAPRELSA REMS Program can prescribe CAPRELSA.

- 2) The pharmacy must have a system in place to verify that the prescriber is enrolled in the CAPRELSA REMS Program each time CAPRELSA is dispensed. If the prescriber is not enrolled, CAPRELSA cannot be dispensed.
- 3) All pharmacy staff and critical employees involved in the dispensing of CAPRELSA will be educated on the requirements of the CAPRELSA REMS Program.
- 4) The pharmacy will maintain a system, records, and documentation that can be audited to document compliance with the CAPRELSA REMS Program, including prescriber certification each time CAPRELSA is dispensed.
- 5) Complete the *CAPRELSA REMS Pharmacy Enrollment Form* and submit it to the CAPRELSA REMS Program.

The *CAPRELSA REMS Pharmacy Enrollment Form* is part of the CAPRELSA REMS Program and is appended.

B. Implementation System

1. Genzyme must ensure that pharmacies (including pharmacy distributors) dispensing CAPRELSA are specially certified using the criteria described above.
2. Genzyme must ensure that distributors who distribute CAPRELSA are specially certified. Specially certified distributors must agree to:
 - a. Distribute CAPRELSA only to pharmacies certified in the CAPRELSA REMS Program.
 - b. Put processes and procedures in place to ensure that the requirements of the CAPRELSA REMS Program are followed.
 - c. Agree to be audited to ensure that CAPRELSA is distributed according to the CAPRELSA REMS Program.
3. Genzyme must maintain a secure, validated, interactive, web-based database of all enrolled entities (prescribers, pharmacies, and distributors). Prescribers will be able to enroll in the program by completing the enrollment requirements online or by calling the CAPRELSA Program Coordinating Call Center at 1-800-817-2722. Certified pharmacies can access the database to verify prescriber enrollment status as required by the REMS.
4. Genzyme must monitor distribution and prescription data to ensure that only enrolled distributors are distributing, enrolled pharmacies are dispensing, and enrolled prescribers are prescribing CAPRELSA. Corrective action must be initiated by Genzyme for prescribers, pharmacies, or distributors who are found not to be complying with the CAPRELSA REMS Program.
 - a. Inpatients in acute care settings will be shipped drug per patient if the prescriber is enrolled in the CAPRELSA REMS Program.

- b. Patients in long-term care facilities will be shipped drug per patient if the prescriber is enrolled in the CAPRELSA REMS Program.
- 5. Genzyme must monitor and audit the online enrollment database, distribution, and dispensing systems to check that all processes and procedures are in place and functioning to support the requirements of the CAPRELSA REMS Program.
- 6. Genzyme must maintain a Program Coordinating Center with a Call Center to support prescribers, pharmacies, and distributors in interfacing with the CAPRELSA REMS Program and CAPRELSA REMS Program website (www.caprelsarems.com) that must continue for the duration of the REMS. Genzyme must ensure that all materials listed in or appended to the CAPRELSA REMS Program will be available through the CAPRELSA REMS website (www.caprelsarems.com) and by calling the CAPRELSA Program Coordinating Call Center at 1-800-817-2722.
- 7. Genzyme must ensure that within 60 calendar days of REMS modification the REMS materials listed in or appended to the CAPRELSA REMS document are available through the CAPRELSA REMS Program Website and by calling the CAPRELSA REMS Program Call Center.
- 8. Based on monitoring and evaluation of these elements to assure safe use, Genzyme must take reasonable steps to improve implementation of these elements and to maintain compliance with the CAPRELSA REMS Program requirements, as applicable.
- 9. Genzyme must train appropriate personnel, and develop and follow written procedures and scripts to implement the CAPRELSA REMS Program. Genzyme will modify them as required based on the results of assessments.

III. TIMETABLE FOR SUBMISSION OF ASSESSMENTS

Genzyme must submit assessments to the FDA annually On the date of the initial approval of the CAPRELSA REMS (April 6, 2011). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date of the assessment. Genzyme must submit each assessment so that it will be received by the FDA on or before the due date.

Appendix 1 *CAPRELSA REMS Prescriber Training Pamphlet*



REMS PROGRAM
RISK EVALUATION AND MITIGATION STRATEGY

**CAPRELSA[®] (vandetanib) Tablets and
Risk of QT Prolongation, Torsades de
Pointes and Sudden Death**

Prescriber Training Pamphlet



Introduction

This training pamphlet has been developed as part of a REMS program to help educate healthcare providers on the **serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of CAPRELSA[®] (vandetanib) Tablets.**

Because of these serious risks, CAPRELSA is only available through the CAPRELSA Risk Evaluation and Mitigation Strategy (REMS) Program. Under the CAPRELSA REMS Program, **only certified prescribers and pharmacies** are able to prescribe and dispense CAPRELSA.

This pamphlet includes information about the serious risks associated with use of CAPRELSA, prescriber certification and enrollment, and how to help mitigate these serious risks through:

- Appropriate patient selection
- Electrocardiogram (ECG) monitoring
- Electrolyte monitoring
- Drug interaction awareness
- Appropriate dosing and administration

This pamphlet focuses on the serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of CAPRELSA. These are not the only risks associated with use of CAPRELSA. Please see the accompanying Prescribing Information for CAPRELSA, including the Boxed Warning.

Please see boxed WARNING on page 3 and accompanying Prescribing Information.

Indication

CAPRELSA® (vandetanib) Tablets 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 progressive disease only after careful consideration of the treatment related risks of CAPRELSA.

Boxed WARNING

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.**



QT Prolongation, Torsades de Pointes, and Sudden Death

- QT Prolongation, Torsades de pointes, ventricular tachycardia, and sudden deaths have occurred in patients treated with CAPRELSA® (vandetanib) Tablets
- CAPRELSA can prolong the QT interval in a concentration-dependent manner
 - In 231 medullary thyroid cancer patients randomized to receive CAPRELSA 300 mg once daily in the phase 3 clinical trial, CAPRELSA was associated with sustained plasma concentration-dependent QT prolongation

	CAPRELSA 300 mg N=231		Placebo N=99	
	All Grades	Grade 3-4	All Grades	Grade 3-4
ECG QT prolonged	14%	8%	1%	1%

- Among all patients who received CAPRELSA, 69% had QT prolongation > 450 ms and 7% had QT prolongation > 500 ms by ECG using Fridericia correction (QTcF)
- Based on the exposure-response relationship, among all patients who received CAPRELSA, the mean (90% CI) QTcF change from baseline (Δ QTcF) was 35 (33-36) ms for the 300-mg dose. The Δ QTcF remained above 30 ms for the duration of the trial (up to 2 years)
- 36% of patients who received CAPRELSA experienced greater than 60 ms increase in Δ QTcF
- Because of the 19-day half-life, adverse reactions including a prolonged QT interval may not resolve quickly. Monitor appropriately

Please see boxed WARNING on page 3 and accompanying Prescribing Information.

Patient Selection

CAPRELSA® (vandetanib) Tablets are approved 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.

In addition when thinking about the risks of QT prolongation, Torsades de pointes and sudden death associated with CAPRELSA, consider the following when deciding if a patient is appropriate for CAPRELSA treatment:

Considerations for Patient Selection

- **Do not use CAPRELSA in patients with:**
 - Congenital long QT syndrome
 - Torsades de pointes
 - Bradyarrhythmias or
 - Uncompensated heart failure
- **Do not start CAPRELSA treatment in patients whose QTcF interval is greater than 450 ms**
- **CAPRELSA has not been studied in patients with ventricular arrhythmias or recent myocardial infarction**
- **Vandetanib exposure is increased in patients with impaired renal function defined as a creatinine clearance <50 mL/min**

Please note that there are other considerations when deciding if CAPRELSA is the appropriate treatment. This material focuses on the risks of QT prolongation, Torsades de pointes, and sudden death associated with CAPRELSA. These are not the only risks associated with CAPRELSA. Please see the Prescribing Information for CAPRELSA, including the boxed WARNING.



ECG Monitoring

- Obtain an ECG:
 - At baseline
 - 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA[®] (vandetanib) Tablets and every 3 months thereafter
 - Following any dose reduction for QT prolongation or any dose interruptions > 2 weeks (monitor as described above)
- Stop CAPRELSA in patients who develop a QTcF greater than 500 ms until the QTcF returns to less than 450 ms. CAPRELSA can then be resumed at a reduced dose
- Monitor ECGs more frequently in patients

Electrolyte Monitoring

- To help reduce the risk of QT prolongation:
 - Maintain serum potassium levels of ≥ 4 mEq/L (within normal range)
 - Maintain serum magnesium and calcium levels within normal ranges
- Obtain 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
- Monitor electrolytes more frequently in patients who experience diarrhea. In the clinical trial, diarrhea occurred more frequently in patients treated with CAPRELSA compared to placebo

	CAPRELSA 300 mg N=231		Placebo N=99	
	All Grades	Grade 3-4	All Grades	Grade 3-4
Diarrhea/ colitis	57%	11%	27%	2%

Please see boxed WARNING on page 3 and accompanying Prescribing Information.

Drug Interactions

- Avoid the administration of CAPRELSA® (vandetanib) Tablets with agents that may prolong the QT interval or are associated with Torsades de pointes
 - These include antiarrhythmic drugs (including but not limited to amiodarone, disopyramide, procainamide, sotalol, dofetilide) and other drugs (including but not limited to chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide)
 - For lists of other possible or conditional risk drugs, please visit the CredibleMeds™ website at www.azcert.org¹
- If drugs known to prolong the QT interval are given to patients already receiving CAPRELSA and no alternative therapy exists, perform ECG monitoring of the QT interval more frequently

Reference: 1. CredibleMeds™. QT drug lists by risk groups. <http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm>. Accessed April 26, 2016.

Dosing and Administration

- The recommended dose of CAPRELSA is 300 mg taken orally once daily until disease progression or unacceptable toxicity occurs
- The 300 mg daily dose can be reduced to 200 mg (two 100 mg tablets) and then to 100 mg for CTCAE (Common Terminology Criteria for Adverse Events) grade 3 or greater toxicities
- Reduce the starting dose to 200 mg in patients with moderate (creatinine clearance ≥ 30 to < 50 mL/min) and severe (creatinine clearance < 30 mL/min) renal impairment
- CAPRELSA may be taken with or without food
- Do not take a missed dose within 12 hours of the next dose.
- CAPRELSA is available as 100 mg tablets and 300 mg tablets



Prescriber Certification in the CAPRELSA® (vandetanib) Tablets REMS Program

Only prescribers certified with the CAPRELSA REMS Program are able to prescribe CAPRELSA

In order to prescribe CAPRELSA, you must:

Review the *CAPRELSA REMS Prescriber Training Pamphlet* or *CAPRELSA REMS Prescriber Training Slide Deck* and the Prescribing Information

Step 1



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

Step 2



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

Step 3



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

Step 4

You are now ready to prescribe and to do so you can download the CAPRELSA Prescription Form at www.caprelsarems.com

To ENROLL, visit www.caprelsarems.com or call 1-800-817-2722.

Please see boxed WARNING on page 3 and accompanying Prescribing Information.

Prescriber Responsibilities

After you enroll in the CAPRELSA REMS Program, remember to:

Talk to your patients about the risks of QT prolongation, Torsades de pointes, and sudden death as well as the other risks associated with CAPRELSA treatment



Review the **CAPRELSA Patient Brochure** with the patient or caregiver before starting treatment



Monitor your patients as outlined in the Prescribing Information and this pamphlet



Report any cases of QT prolongation, Torsades de pointes and/or sudden death to 1-800-745-4447

Pharmacy Certification

Only pharmacies certified with the CAPRELSA REMS Program are able to dispense CAPRELSA

- CAPRELSA is available through Biologics Inc. Call 1-800-367-4999 or go to www.biologics.today.com for more information
- A prescription form is available at www.caprelsarems.com



**Please see accompanying Prescribing Information
for CAPRELSA.**

Reference ID: 4098675



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Appendix 2 *CAPRELSA REMS Prescriber Training Slide Deck*



Prescriber Training Slide Deck



Contents

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CAPRELSA[®] (vandetinib) Tablets

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- Patient Selection
- ECG and Electrolyte Monitoring
- Drug Interactions
- Dosing and Administration

CAPRELSA REMS Program Information

- Prescriber Certification
- Pharmacy Certification



Introduction

- This presentation has been developed as part of the CAPRELSA REMS Program, a restricted distribution program, to mitigate the serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of CAPRELSA[®] (vandetanib) 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



Indication

CAPRELSA® (vandetanib) 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.



BOXED WARNING: QT Prolongation, Torsades de Points, and Sudden Death

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

- CAPRELSA® (vandetanib) Tablets 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.



Risk of QT Prolongation, Torsades de pointes, and Sudden Death

- QT prolongation, Torsades de pointes, ventricular tachycardia, and sudden deaths have occurred in patients receiving CAPRELSA® (vandetanib) Tablets
- CAPRELSA can prolong the QT interval in a concentration-dependent manner
 - In 231 medullary thyroid cancer patients randomized to receive CAPRELSA 300 mg once daily in the phase 3 clinical trial, CAPRELSA was associated with sustained plasma concentration-dependent QT prolongation

	CAPRELSA 300 mg (N=231)		Placebo (N=99)	
	All Grades	Grade 3-4	All Grades	Grade 3-4
ECG QT prolonged	14%	8%	1%	1%



Risk of QT Prolongation, Torsades de pointes, and Sudden Death *(continued)*

- In the phase 3 medullary thyroid cancer clinical trial:
 - Among all patients who received CAPRELSA® (vandetanib) Tablets, 69% had QT prolongation >450 ms and 7% had QT prolongation >500 ms by ECG using Fridericia correction (QTcF)
 - Based on the exposure-response relationship, among all patients who received CAPRELSA, the mean (90% CI) QTcF change from baseline (Δ QTcF) was 35 (33-36) ms for the 300-mg dose. The Δ QTcF remained above 30 ms for the duration of the trial (up to 2 years)
 - 36% of patients who received CAPRELSA experienced greater than 60 ms increase in Δ QTcF
- Because of the 19-day half-life, adverse reactions including a prolonged QT interval may not resolve quickly. Monitor appropriately



Patient Selection

- Do not use CAPRELSA[®] (vandetanib) in patients with:
 - Congenital long QT syndrome
 - Torsades de pointes
 - Bradyarrhythmias or
 - Uncompensated heart failure
- Do not start CAPRELSA treatment in patients whose QTcF interval is > 450 ms
- CAPRELSA has not been studied in patients with ventricular arrhythmias or recent myocardial infarction
- Vandetanib exposure is increased in patients with impaired renal function defined as a creatinine clearance < 50 mL/min
- This presentation focuses on the risks of QT prolongation, Torsades de pointes, and sudden death associated with CAPRELSA. These are not the only risks associated with CAPRELSA. Please see the full Prescribing Information for CAPRELSA, including the boxed WARNING

ECG Monitoring

- Obtain an ECG:
 - At baseline
 - 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA® (vandetanib) Tablets, and every 3 months thereafter
 - Following any dose reduction for QT prolongation or any dose interruptions > 2 weeks, conduct QT assessments as described above
- Stop CAPRELSA in patients who develop a QTcF > 500 ms until the QTcF returns to < 450 ms. Dosing of CAPRELSA can then be resumed at a reduced dose
- Monitor ECGs more frequently in patients who experience diarrhea



Electrolyte Monitoring

- To help reduce the risk of QT prolongation:
 - Maintain serum potassium levels of ≥ 4 mEq/L (within normal range)
 - Maintain serum magnesium and calcium levels within normal ranges
- Obtain serum potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH):
 - At baseline
 - 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA[®] (vandetanib) Tablets, and every 3 months thereafter
- Monitor electrolytes more frequently in patients who experience diarrhea. In the clinical trial, diarrhea occurred more frequently in patients treated with CAPRELSA[®] (vandetanib) Tablets compared to placebo

	CAPRELSA 300 mg (N=231)		Placebo (N=99)	
	All Grades	Grade 3-4	All Grades	Grade 3-4
Diarrhea/Colitis	57%	11%	27%	2%



Drug Interactions

- Avoid administration of CAPRESLA[®] (vandetanib) Tablets with anti-arrhythmic drugs and other drugs known to prolong the QT interval
 - These include:
 - **Antiarrhythmic drugs:** Including but not limited to amiodarone, disopyramide, procainamide, sotalol, dofetilide
 - **Other drugs:** Including but not limited to chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide
 - For lists of other possible or conditional risk drugs, please visit the CredibleMeds[™] web site at www.azcert.org¹
- If such drugs are given to patients already receiving CAPRELSA and no alternative therapy exists, perform ECG monitoring of the QT interval more frequently.

1. CredibleMeds[™]. QT drug lists by risk groups. <http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm>. Accessed June 15, 2016

Dosing and Administration

- The recommended dose of CAPRELSA® (vandetanib) Tablets is 300 mg taken orally once daily until disease progression or unacceptable toxicity occurs.
- The 300 mg daily dose can be reduced to 200 mg (two 100 mg tablets) and then to 100 mg for CTCAE grade 3 or greater toxicities
- Reduce the starting dose to 200 mg in patients with moderate (creatinine clearance ≥ 30 to < 50 mL/min) and severe (creatinine clearance < 30 mL/min) renal impairment
- CAPRELSA may be taken with or without food
- Do not take a missed dose within 12 hours of the next dose
- CAPRELSA is available as 100 mg tablets and 300 mg tablets

CTCAE=Common Terminology Criteria for Adverse Events



Prescriber Certification in the CAPRELSA REMS Program

- **Only prescribers certified with the CAPRELSA REMS Program are able to prescribe CAPRELSA® (vandetanib) Tablets**
 - In order to prescribe CAPRELSA, you must:
 - **Step 1:** Review this *CAPRELSA REMS Prescriber Training Pamphlet* or *CAPRELSA REMS Prescriber Training Slide Deck* and the CAPRELSA Prescribing Information
 - **Step 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
 - **Step 3:** Continue with the enrollment process by completing the *CAPRELSA REMS Prescriber Training Questions* online or by calling the CAPRELSA REMS Program
 - **Step 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



Prescriber Responsibilities

After you enroll in the CAPRELSA REMS Program:

- Talk to your patients about the risks of QT prolongation, Torsades de pointes, and sudden death as well as the other risks associated with CAPRELSA[®] (vandetanib) treatment
- Review the CAPRELSA Patient Brochure with the patient or caregiver before starting treatment
- Monitor your patients as outlined in the Prescribing Information and this presentation
- Report any cases of QT prolongation, Torsades de pointes and/or sudden death to 1-800-745-4447



Pharmacy Certification in the CAPRELSA REMS Program

- **Only pharmacies certified with the CAPRELSA REMS Program are able to dispense CAPRELSA[®] (vandetanib)**
 - CAPRELSA is available through Biologics Inc.
Call 1-800-367-4999 or go to www.biologics.today.com
for more information
 - A prescription form is available at
www.caprelsarems.com



Appendix 3 *CAPRELSA REMS Prescriber Training Questions*

Prescriber Training Questions

The goal of the Prescriber Training Program is to help ensure that prescribers treating patients with **CAPRELSA**[®] (vandetanib) Tablets understand the risk for QT prolongation, Torsades de pointes and sudden death associated with CAPRELSA treatment. These are not the only risks associated with CAPRELSA. Please see the Prescribing Information for additional Warnings and Precautions and safety information on CAPRELSA.

Review each of the six sections and answer the question following each section. Select the one answer that is the best choice for each question. This 6-question assessment should take approximately 15 minutes to complete.

QT Prolongation, Torsades de pointes, and Sudden Death

- Torsades de pointes, ventricular tachycardia, and sudden deaths have occurred in patients treated with CAPRELSA® (vandetanib) Tablets
- CAPRELSA can prolong the QT interval in a concentration-dependent manner
 - In 231 medullary thyroid cancer patients randomized to receive CAPRELSA 300 mg once daily in the phase 3 clinical trial, CAPRELSA was associated with sustained plasma concentration-dependent QT prolongation.

	CAPRELSA 300 mg N=231		Placebo N=99	
	All Grades	Grade 3-4	All Grades	Grade 3-4
ECG QT Prolonged	14%	8%	1%	1%

- Among all patients who received CAPRELSA, 69% had QT prolongation >450 ms and 7% had QT prolongation >500 ms by ECG using Fridericia correction (QTcF)
- Based on the exposure-response relationship, among all patients who received CAPRELSA, the mean (90% CI) QTcF change from baseline (Δ QTcF) was 35 (33-36) ms for the 300-mg dose. The Δ QTcF remained above 30 ms for the duration of the trial (up to 2 years).
- 36% of patients who received CAPRELSA experienced greater than 60 ms increase in Δ QTcF
- Because of the 19-day half-life, adverse reactions including prolonged QT interval may not resolve quickly. Monitor appropriately

Q1. According to the Prescribing Information, QT prolongation, Torsades de pointes and sudden death have occurred in patients treated with CAPRELSA® (vandetanib) Tablets. CAPRELSA can prolong the QT interval in a concentration-dependent manner. Because of the 19-day half life, adverse reactions including prolonged QT interval may not resolve quickly

- a. All the above statements are True
 - b. All the above statements are False
-

Patient Selection

CAPRELSA[®] (vandetanib) Tablets are approved 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.

In addition when thinking about the risks of QT prolongation, Torsades de pointes and sudden death associated with CAPRELSA, consider the following when deciding if a patient is appropriate for CAPRELSA treatment:

- Do not use CAPRELSA in patients with
 - Congenital long QT syndrome
 - Torsades de pointes
 - Bradyarrhythmias or
 - Uncompensated heart failure
- Do not start CAPRELSA treatment in patients whose QTcF interval is greater than 450 ms
- CAPRELSA has not been studied in patients with ventricular arrhythmias or recent myocardial infarction
- Vandetanib exposure is increased in patients with impaired renal function defined as a creatinine clearance <50 mL/min

Please note that there are other considerations when deciding if CAPRELSA is the appropriate treatment. This material focuses on the risks of QT prolongation, Torsades de pointes, and sudden death associated with CAPRELSA. These are not the only risks associated with CAPRELSA. Please see the full Prescribing Information for CAPRELSA, including the boxed WARNING.

Q2. According to the Prescribing Information for CAPRELSA[®] (vandetanib) Tablets, which of the following statements is true?

- a. CAPRELSA is contraindicated in patients with congenital long QT syndrome
 - b. CAPRELSA should not be administered to patients with a history of Torsades de pointes, bradyarrhythmias, or uncompensated heart failure
 - c. CAPRELSA should not be started in patients with a QTcF interval greater than 450 ms
 - d. All the above
-

ECG Monitoring

- Obtain an ECG:
 - At baseline
 - 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA[®] (vandetanib) Tablets and every 3 months thereafter
 - Following any dose reduction for QT prolongation or any dose interruptions >2 weeks (monitor as described above)
- Stop CAPRELSA in patients who develop a QTcF greater than 500 ms until the QTcF returns to less than 450 ms. CAPRELSA can then be resumed at a reduced dose
- Monitor ECGs more frequently in patients who experience diarrhea

Q3. According to the Prescribing Information, patients who develop a QTcF greater than 500 ms while on CAPRELSA[®] (vandetanib) Tablets treatment should:

- a. Continue CAPRELSA without interruption, at the current dose
 - b. Continue CAPRELSA without interruption, but at a reduced dose
 - c. Stop taking CAPRELSA until QTcF returns to less than 450 ms. Dosing of CAPRELSA can be resumed at a reduced dose.
 - d. None of the above
-

Electrolyte Monitoring

- To help reduce the risk of QT prolongation:
 - Maintain serum potassium levels at ≥ 4 mEq/L (within normal range)
 - Maintain serum magnesium and calcium levels within normal ranges
- Obtain serum potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH):
 - At baseline
 - 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA[®] (vandetanib) Tablets and every 3 months thereafter
- Monitor electrolytes more frequently in patients who experience diarrhea. In the clinical trial, diarrhea occurred more frequently in patients treated with CAPRELSA compared to placebo

	CAPRELSA 300 mg N=231		Placebo N=99	
	All Grades	Grade 3-4	All Grades	Grade 3-4
Diarrhea/colitis	57%	11%	27%	2%

Q4. According to the Prescribing Information, to help reduce the risk of electrocardiogram QT prolongation with CAPRELSA[®] (vandetanib) Tablets:

- a. Serum potassium levels should be maintained at 4mEq/L or higher (within normal range)
 - b. Serum magnesium levels should be maintained within normal range
 - c. Serum calcium levels should be maintained within normal range
 - d. All the above
-

Drug Interactions

- Avoid the administration of CAPRELSA[®] (vandetanib) Tablets with agents that may prolong the QT interval or are associated with Torsades de pointes
 - These include antiarrhythmic drugs (including but not limited to amiodarone, disopyramide, procainamide, sotalol, dofetilide) and other drugs (including but not limited to chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide)
 - For lists of other possible or conditional risk drugs, please visit the CredibleMeds[™] web site at www.azcert.org¹
- If drugs known to prolong the QT interval are given to patients already receiving CAPRELSA and no alternative therapy exists, perform ECG monitoring of the QT interval more frequently

References: 1. CredibleMeds[™]. QT drug lists by risk groups. <http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm>. Accessed June 15, 2016.

Q5. According to the Prescribing Information, administration of CAPRELSA[®] (vandetanib) Tablets should be avoided in patients who are also receiving other drugs which include:

- a. Drugs that may prolong QT interval
 - b. Anti-arrhythmic drugs
 - c. a and b
 - d. None of the above
-

Dosing and Administration

- The recommended dose of CAPRELSA[®] (vandetanib) Tablets is 300 mg taken orally once daily until disease progression or unacceptable toxicity occurs
- The 300 mg daily dose can be reduced to 200 mg (two 100 mg tablets) and then to 100 mg for CTCAE (Common Terminology Criteria for Adverse Events) grade 3 or greater toxicities
- Reduce the starting dose to 200 mg in patients with moderate (creatinine clearance ≥ 30 to < 50 mL/min) and severe (creatinine clearance < 30 mL/min) renal impairment
- CAPRELSA may be taken with or without food
- Do not take a missed dose within 12 hours of the next dose.
- CAPRELSA is available as 100 mg tablets and 300 mg tablets

-
- Q6. According to the Prescribing Information, if a patient misses a dose of CAPRELSA[®] (vandetanib) Tablets:
- a. The missed dose should be taken by the patient at any time
 - b. The missed dose should not be taken by the patient if it is less than 12 hours before the next dose
 - c. The missed dose should be taken along with the next dose
 - d. None of the above
-

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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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Appendix 5 *CAPRELSA REMS Pharmacy Enrollment Form*

A designated authorized pharmacist from the pharmacy must enroll and be certified by the CAPRELSA REMS Program before the pharmacy can dispense CAPRELSA[®] (vandetanib) Tablets for Oral use.

Pharmacy Information

Pharmacy Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

National Provider Identifier (NPI): _____ State License Number: _____

NCPDP Number: _____

1. I understand that CAPRELSA is only available through the CAPRELSA REMS Program and I and pharmacy staff must comply with the program requirements. In addition, as the designated authorized pharmacist, I acknowledge that:
 - a. I understand that only prescribers enrolled in the CAPRELSA REMS Program can prescribe CAPRELSA.
 - b. The pharmacy must have a system in place to verify that the prescriber is enrolled in the CAPRELSA REMS Program each time CAPRELSA is dispensed. If the prescriber is not enrolled, CAPRELSA cannot be dispensed.
 - c. All pharmacy staff and critical employees involved in the dispensing of CAPRELSA will be educated on the risks and requirements of the CAPRELSA REMS Program.
 - d. The pharmacy will ensure that it has adequate processes and procedures in place and that those processes and procedures are being followed for the CAPRELSA REMS Program.
 - e. The pharmacy will maintain a system, records and documentation that can be audited to document compliance with the CAPRELSA REMS Program; including prescriber certification each time CAPRELSA is dispensed.

Designated Authorized Pharmacist Signature: _____

Date _____

Title: _____ First Name: _____ Last Name: _____

Phone Number: _____ E-mail: _____

If you have any enrollment questions, please call 1-800-817-2722
Please visit www.caprelsarems.com for more information

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Appendix 6 *CAPRELSA Patient Brochure*



CAPRELSA® PATIENT BROCHURE

What do you need to know about CAPRELSA?

What is CAPRELSA?

CAPRELSA is a prescription medicine used to treat medullary thyroid cancer that cannot be removed by surgery or that has spread to other parts of the body.

What are the most serious risks of CAPRELSA?

CAPRELSA can cause a change in the electrical activity of your heart called QT prolongation, which can cause irregular heartbeats that may lead to death.

You should not take CAPRELSA if you have had a condition called long QT syndrome since birth.

Your prescriber should perform the following tests:

- Check the levels of your blood potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH)
- Check the electrical activity of your heart, using a device called an electrocardiogram (ECG)

These tests should be performed before starting CAPRELSA and regularly during CAPRELSA treatment.

What are the signs and symptoms of QT prolongation?

- Feeling faint
- Feeling light-headed
- Feeling your heart beating irregularly

Call your prescriber right away if you experience these signs or symptoms.

The CAPRELSA REMS Program

Because of the risk of QT prolongation, CAPRELSA is only available through a program called the CAPRELSA Risk Evaluation and Mitigation (REMS) Program.

Your prescriber will discuss the benefits and risks of CAPRELSA with you.

How do I receive CAPRELSA?

CAPRELSA is only available through a REMS Certified Pharmacy. Your prescriber will submit your CAPRELSA prescription to Biologics, Inc. The certified pharmacy will call you to arrange the date to ship CAPRELSA to you. You can contact Biologics, Inc. about your prescription at 1-800-367-4999.

This brochure only discusses the most serious risks of CAPRELSA and the CAPRELSA REMS Program. For more information about CAPRELSA please see the CAPRELSA Medication Guide available at www.caprelsarems.com.



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Reference ID: 4098675



Appendix 7 *CAPRELSA REMS Program Website Screenshots*

Prescribing CAPRELSA

Prescribing Information for CAPRELSA 

CAPRELSA Prescription Form 

CAPRELSA Patient Brochure 

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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 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.

CAPRELSA REMS Program: Learn and Enroll

[Learn About the CAPRELSA REMS Program »](#)

[Enroll in the CAPRELSA REMS 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.

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Prescribing CAPRELSA

Prescribing Information
for CAPRELSA 

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CAPRELSA Patient
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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](#) 

Next: [Learn About the CAPRELSA REMS 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.*

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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 1-800-817-2722.

Distribution of CAPRELSA

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

Next: [Contact Us](#)

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

Only certified prescribers can prescribe CAPRELSA.
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Wednesday, July 20, 2016



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[Resume Enrollment](#)

Pharmacies

[Verify Prescriber Enrollment](#)

Version: 1.14.0.2 (1.3.1)

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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.

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/s/

JEFFERY L SUMMERS
05/16/2017