RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

The goal of the SILIQ REMS Program is to mitigate the observed risk of suicidal ideation and behavior, including completed suicides, which occurred in subjects treated with SILIQ by:

- Ensuring that prescribers are educated about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to counsel patients about this risk.
- Ensuring that patients are informed about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to seek medical attention for manifestations of suicidal thoughts and behavior, new onset or worsening depression, anxiety, or other mood changes.

II. ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe SILIQ must be certified.
   a. To become certified to prescribe SILIQ, prescribers must:
      i. Review the Prescribing Information (PI) for SILIQ.
      ii. Enroll in the SILIQ REMS Program by completing the SILIQ REMS Program Prescriber Enrollment Form
   b. As a condition of certification, prescribers must:
      i. Enroll each patient in the SILIQ REMS Program by performing the following:
         1) Prior to providing the first prescription, counsel the patient that suicidal ideation and behavior (SIB), including completed suicides, have occurred in patients treated with SILIQ by informing the patient of the following key safety information:
            i. Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.
            ii. To be aware of symptoms of suicidal ideation and behavior (SIB) events and steps to take if SIB symptoms occur.
         2) Complete the SILIQ REMS Program Patient-Prescriber Agreement Form for each patient. Submit the completed form to the SILIQ REMS Program and store a copy in the patient’s records.
         3) Provide the patient with the SILIQ REMS Program Patient Wallet Card
            i. Understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.
ii. Inform SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under your care.

c. Valeant Pharmaceuticals North America LLC (Valeant) must:
   i. Ensure that healthcare providers who prescribe SILIQ are certified, in accordance with the requirements described above.
   ii. Provide all the following mechanisms for prescribers to complete the certification process for the SILIQ REMS Program: online, by email, and by fax.
   iii. Ensure that prescribers are notified when they have been certified by the SILIQ REMS Program.
   iv. Maintain a validated, secure database of prescribers who are certified to prescribe SILIQ in the SILIQ REMS Program.
   v. Ensure that prescribers meet the REMS requirements and de-certify prescribers who do not maintain compliance with REMS requirements.
   vi. Ensure that certified prescribers are provided access to the database of certified pharmacies and enrolled patients.
   vii. Provide the SILIQ REMS Program Prescriber Enrollment Form, SILIQ REMS Program Patient-Prescriber Agreement Form, SILIQ REMS Program Patient Wallet Card, and the Prescribing Information to healthcare providers who (1) attempt to prescribe SILIQ and are not yet certified, or (2) inquire about how to become certified.

The following materials are part of the REMS and are appended:
   - SILIQ REMS Program Prescriber Enrollment Form
   - SILIQ REMS Program Patient-Prescriber Agreement Form
   - SILIQ REMS Program Patient Wallet Card

2. Pharmacies that dispense SILIQ must be certified.
   a. To become certified to dispense SILIQ, pharmacies must:
      i. Designate an authorized representative to complete the enrollment process by submitting the completed SILIQ REMS Program Pharmacy Enrollment Form on behalf of the pharmacy.
      ii. Ensure that the authorized representative oversees implementation and compliance with the SILIQ REMS Program requirements by the following:
         1) Review and complete the SILIQ REMS Program Pharmacy Enrollment Form.
         2) Ensure all relevant staff involved in the dispensing of SILIQ are informed of the SILIQ REMS Program requirements as described in the SILIQ REMS Program Pharmacy Enrollment Form.
         3) Put processes and procedures in place to ensure the following requirements are completed prior to dispensing SILIQ:
            1. Verify the prescriber is certified and the patient is enrolled in the SILIQ REMS Program by calling the SILIQ REMS Program or by accessing the SILIQ REMS Program Website.

   b. As a condition of certification, the certified pharmacies must:
i. Recertify in the SILIQ REMS Program if the pharmacy designates a new authorized representative.

ii. Dispense SILIQ to patients only after obtaining authorization by calling the SILIQ REMS Program or by accessing the SILIQ REMS Program Website. The authorization confirms the following:
   1) The prescriber is certified in the SILIQ REMS Program; and
   2) The patient is enrolled in the SILIQ REMS Program

iii. Maintain documentation that all processes and procedures are in place and are being followed for the SILIQ REMS Program and provide upon request to Valeant, FDA, or a third party acting on behalf of Valeant or FDA.

iv. Comply with audits by Valeant, FDA, or a third party acting on behalf of Valeant or FDA, to ensure that all processes and procedures are in place and are being followed for the SILIQ REMS Program.

c. Valeant must:
   i. Ensure that pharmacies that dispense SILIQ are specially certified, in accordance with the requirements described above.
   ii. Provide all the following mechanisms for pharmacies to complete certification for the SILIQ REMS Program: online, by email, and by fax.
   iii. Ensure that pharmacies are notified when they have been certified by the SILIQ REMS Program.
   iv. Ensure that certified pharmacies are provided access to the database of certified prescribers and enrolled patients.
   v. Verify every year that the authorized representative’s name and contact information correspond to those of the currently designated authorized representative for the certified pharmacy. If different, the pharmacy must be required to recertify with a new authorized representative.

The following materials are part of the REMS and are appended:

- *SILIQ REMS Program Pharmacy Enrollment Form*
- *SILIQ REMS Program Website (www.SILIQREMS.com)*

3. **SILIQ must be dispensed to patients with evidence or other documentation of safe-use conditions.**
   
a. To become enrolled in the SILIQ REMS Program, a patient must sign a *SILIQ REMS Program Patient-Prescriber Agreement Form* indicating that he/she has:
   i. Received and has read the *SILIQ REMS Program Patient-Prescriber Agreement Form* with their healthcare provider.
   ii. Received counseling from the prescriber regarding:
      1) the observed risk of suicidal ideation and behavior (SIB)
      2) the importance of keeping the *SILIQ REMS Program Patient Wallet Card* with them at all times
      3) the need to seek medical attention should they experience emergence or worsening of suicidal ideation and behavior
   iii. Received the *SILIQ REMS Program Patient Wallet Card*
b. Valeant must:
   i. Provide all of the following mechanisms for the certified prescribers to be able to submit the completed *SILIQ REMS Program Patient-Prescriber Agreement Form* to the SILIQ REMS Program: online, by email, and by fax.

The following materials are part of the REMS and are appended:
   - *SILIQ REMS Program Patient Wallet Card*
   - *SILIQ REMS Program Patient-Prescriber Agreement Form*

**B. Implementation System**

1. Valeant must ensure that SILIQ is only distributed to certified pharmacies by:
   
   a. Ensuring that wholesalers/distributors who distribute SILIQ comply with the program requirements for wholesalers/distributors. The wholesalers/distributor must:
      
      i. Put processes and procedures in place to verify, prior to distributing SILIQ, that the pharmacies are certified.
      ii. Train all relevant staff on the SILIQ REMS Program requirements.
      iii. Comply with audits by Valeant, FDA, or a third party acting on behalf of Valeant or FDA to ensure that all processes and procedures are in place and are being followed for the SILIQ REMS Program. In addition, wholesalers/distributors must maintain documentation to support that all processes and procedures are in place, being followed, and make the documentation available for audits.
      iv. Provide distribution data to Valeant to verify compliance with the REMS.

   b. Ensuring that wholesalers/distributors maintain distribution records of all shipments of SILIQ and provide the data to Valeant.

2. Valeant must monitor distribution data to ensure all the processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program.

3. Valeant must audit the wholesalers/distributors within 90 calendar days after the wholesaler/distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program.

4. Valeant must maintain a validated, secure database of prescribers and pharmacies that are certified to dispense SILIQ in the SILIQ REMS Program.

5. Valeant must maintain a validated, secure database of patients who are enrolled in the SILIQ REMS Program.

6. Valeant must maintain records of SILIQ certified prescribers, certified pharmacies, and enrolled patients to meet REMS requirements.

7. Valeant must maintain a SILIQ REMS Program Call Center (855-511-6135) and SILIQ REMS Program Website (www.SILIQREMS.com). The REMS Program Website must include the capability to confirm patient authorization status, and the option to print the Prescribing Information, Medication Guide, and SILIQ REMS materials. The SILIQ product website must include a prominent REMS-specific link to the
SILIQ REMS Program Website. The SILIQ REMS Program Website must not link back to the product website(s).

8. Valeant must ensure that the SILIQ REMS Program Website is fully operational, including the capability to complete prescriber and pharmacy certification and patient enrollment online; online confirmation of patient authorization functionality; and the REMS materials listed in or appended to the SILIQ REMS document are available through the SILIQ REMS Program Website and by calling the SILIQ REMS Program Call Center.

9. Valeant must monitor on an ongoing basis the certified pharmacies to ensure the requirements of the SILIQ REMS Program are being met. Valeant must institute corrective action if noncompliance is identified and decertify pharmacies that do not maintain compliance with the REMS requirements.

10. Valeant must maintain an ongoing annual audit plan that involves certified pharmacies.

11. Valeant must audit 20% or one, whichever is greater, of the certified pharmacies within 90 calendar days after the pharmacy places its first order of SILIQ to ensure that all processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program. The certified pharmacies must be identified in Valeant’s ongoing annual audit plan. Valeant must institute corrective action if noncompliance is identified.

12. Valeant must take reasonable steps to improve implementation of and compliance with the requirements in the SILIQ REMS Program based on monitoring and evaluation of the SILIQ REMS Program.

III. Timetable for Submission of Assessments

Valeant must submit REMS assessments to the FDA at 6 months and 12 months and annually thereafter from the date of the initial approval of the REMS (February 15, 2017). 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 for that assessment. Valeant must submit each assessment so that it will be received by the FDA on or before the due date.
SILIQ™ REMS Program
Prescriber Enrollment Form

Instructions

Please fax this completed form to the SILIQ Risk Evaluation Mitigation Strategy (REMS) Program at 1-866-227-9451, submit online at www.SILIQREMS.com, or email it to SILIQ@SILIQREMS.com.

SILIQ (brodalumab) is available only through the SILIQ REMS Program. The SILIQ REMS Program is available to answer questions regarding this program and initiating treatment with SILIQ. Please call 1-855-511-6135 for more information.

Only prescribers, pharmacies, and patients enrolled in the SILIQ REMS Program are able to prescribe, dispense and receive SILIQ.

1. Review the one-time SILIQ REMS Enrollment Information for Prescribers, including the Prescribing Information (PI).
2. Complete and submit this SILIQ REMS Program Prescriber Enrollment Form via the program website, email, or the fax number provided.
3. Send your patient’s prescription to a pharmacy that is enrolled in the SILIQ REMS Program by utilizing the Pharmacy Certification Look Up function on the SILIQ REMS Program website.

You will receive enrollment confirmation via your preferred method of communication (email or fax) within 2 business days.

SILIQ Prescriber Information (*Required)

First Name*: 
Last Name*: 
Degree*: □ MD □ DO □ PA □ NP □ Other
National Provider Identification (NPI) Number*: 
DEA Number:
Name of Institution or Healthcare Facility*: 
Specialty*:
Street Address*:
City*: State*: Zip Code*:
Office Phone Number*: Office Fax Number*: Mobile Phone Number:
Email Address: Preferred Method of Communication*: □ Email □ Fax

Prescriber Agreement

By completing this form, I attest that:
1. I have read and understand the SILIQ Prescribing Information.
2. I understand that I must comply with the Program requirements in order to prescribe SILIQ.
3. I understand that by signing this SILIQ REMS Program Prescriber Enrollment Form (one time only), I will be enrolled in the SILIQ REMS Program and may prescribe SILIQ.
4. I understand that, prior to authorizing the first prescription, I am responsible for counseling each patient that suicidal ideation and behavior (SIB), including completed suicides, have occurred in patients treated with SILIQ. I will inform the patient of the following key safety information:
   - Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.
   - To be aware of symptoms of suicidal ideation behavior (SIB) events and steps to take if SIB symptoms occur.
5. I understand that I must submit a completed SILIQ REMS Program Patient-Prescriber Agreement Form for each patient before I prescribe SILIQ for the first time, and store a copy of the completed form in the patient’s record.
6. I will provide each patient with a SILIQ REMS Program Patient Wallet Card and instruct each patient to carry this card with them at all times.
7. I understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.
8. I will inform the SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under my care.
9. I understand Valeant and its agents may contact me via phone, mail, fax, email, or in person to support administration of the SILIQ REMS Program.

Prescriber Signature*: Date*: 

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Reference ID: 4056898
Instructions for Prescribers

1. Sign this form along with your patient and place it in the patient's chart.
2. Tear off the bottom portion and provide it to your patient to take home as a reference.
3. Submit this completed form to the SILIQ Risk Evaluation and Mitigation Strategy (REMS) Program online at www.SILIQREMS.com or by fax at 1-866-227-9451.

Patient Acknowledgement (*Required)

By signing this form, I acknowledge that:

☐ I understand that suicidal thoughts and behavior, including completed suicides, have occurred in patients treated with SILIQ.

☐ I will call my doctor or the National Suicide Prevention Lifeline at 1-800-273-8255 if:
   ○ I feel new or worsening feelings of withdrawal, depression, anxiety, hopelessness, or other mood changes beginning.
   ○ I am thinking about hurting or killing myself; seeking access to firearms, pills or other means for the purpose of self-harm; or am talking or writing about death and dying.

☐ I will call 911 if I feel an immediate threat of death or self-injury.

☐ My doctor has given me a SILIQ REMS Patient Wallet Card to carry with me at all times.

Printed First and Last Name* | Date of Birth (Month/Day/Year)*
---|---
Phone Number* | State* | Zip Code*
Patient Signature* | Date*

Prescriber Acknowledgement

I acknowledge that prior to prescribing SILIQ:

☐ I have counseled my patient about the importance of seeking medical advice should signs of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes emerge.

☐ I have evaluated the risks and benefits of continuing treatment with SILIQ if such events occur.

Printed First and Last Name* | DEA* | NPI*
---|---|---
Phone Number* | Prescriber Signature* | Date*
SILIQTM REMS Program
Pharmacy Enrollment Form

Instructions

To become enrolled, the pharmacy must designate an Authorized Pharmacy Representative to ensure compliance with the SILIQ Risk Evaluation and Mitigation Strategy (REMS) Program.

Please fax this completed form to the SILIQ REMS Program at 1-866-227-9451, submit online at www.SILIQREMS.com, or email it to SILIQ@SILIQREMS.com.

SILIQ (brodalumab) is available only through the SILIQ REMS Program. The SILIQ REMS Program is available to answer questions regarding this program and initiating treatment with SILIQ. Please call 1-855-511-6135 for more information.

Authorized Pharmacy Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the SILIQ REMS Program. By signing this form, I agree, on behalf of myself and my pharmacy, to comply with the following program requirements:

1. I understand that by signing this form, and upon confirmation from the SILIQ REMS Program, this pharmacy will be enrolled in the SILIQ REMS Program, and will be able to order and dispense SILIQ.

2. This pharmacy will re-enroll in the SILIQ REMS Program if the name and contact information for the Authorized Pharmacy Representative changes.

3. This pharmacy will ensure that all relevant staff involved in the dispensing of SILIQ is trained on the SILIQ REMS Program requirements.

4. This pharmacy will maintain and make available appropriate documentation reflecting that all processes and procedures are in place and being followed.

5. I understand that non-compliance with the requirements of the SILIQ REMS Program will result in decertification of my pharmacy and termination of authorization to dispense SILIQ.

6. I will ensure that, prior to dispensing SILIQ, my pharmacy will verify that the prescriber is certified and the patient is enrolled to receive SILIQ by contacting the SILIQ REMS Program.

7. This pharmacy will comply with audits by Valeant, the US Food and Drug Administration (FDA), or a designated third party acting on behalf of Valeant or FDA to ensure compliance with the SILIQ REMS Program.

Pharmacy Information (*Required)

<table>
<thead>
<tr>
<th>Pharmacy Name:*</th>
<th>Pharmacy Type:*</th>
<th>□ Inpatient</th>
<th>□ Outpatient</th>
</tr>
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<tbody>
<tr>
<td>Address:*</td>
<td>City:*</td>
<td>State:*</td>
<td>Zip Code:*</td>
</tr>
<tr>
<td>Pharmacy Identifier:* (at least one required):</td>
<td>NPI:*</td>
<td>NCPDP:*</td>
<td>DEA:*</td>
</tr>
</tbody>
</table>

Authorized Pharmacy Representative Information (*Required)

<table>
<thead>
<tr>
<th>First Name:*</th>
<th>Last Name:*</th>
<th>MI:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone Number:*</td>
<td>Alternate Telephone Number:</td>
<td>Office Fax:*</td>
</tr>
<tr>
<td>Email:*</td>
<td>Preferred Method of Communication:*</td>
<td>□ Email</td>
</tr>
</tbody>
</table>

Authorized Pharmacy Representative Signature:* | Date:*

By completing and submitting this form and receiving enrollment confirmation, your pharmacy will be certified in the SILIQ REMS Program. You will receive confirmation of your enrollment via your preferred method of communication.

Reference ID: 40566989

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SILIQ is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

WARNING: Suicidal thoughts and behavior, including completed suicides, have occurred in patients treated with SILIQ.

Taking SILIQ has proven effective for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. However, if you are experiencing sudden feelings of withdrawal, anxiety, depression or hopelessness, call your doctor immediately. Suicide warning signs also include thinking about hurting or killing yourself; seeking access to firearms, pills or other means for the purpose of self-harm; and talking or writing about death and dying when these actions are out of the ordinary.1,2

Reference ID: 4056898
You are not alone. Help is available.

I will call my doctor or the National Suicide Prevention Lifeline at 1-800-273-8255 (TALK) if:

- I feel new or worsening feelings of withdrawal, depression, anxiety, hopelessness, or other mood changes beginning.
- I am thinking about hurting or killing myself; seeking access to firearms, pills or other means for the purpose of self-harm; or am talking or writing about death and dying\(^2\).

I will call 911 if I feel an immediate threat of death or self-injury.

Learn about the signs of suicide at www.suicidelifeline.org.

For more information, visit www.SILIQREMS.com or call 1-855-511-6135.

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Reference ID: 4056898
SILIQ REMS Program
Website Screen Captures

February 13th, 2017
Version 5.0
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<td>5.5</td>
<td>Edit Authorized Pharmacy Representative Profile</td>
<td>30</td>
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<tr>
<td>5.6</td>
<td>View Pharmacy Profile</td>
<td>31</td>
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<td>5.7</td>
<td>Predispense Authorization (PDA) Intake</td>
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<td>Predispense Authorization (PDA) Confirmation</td>
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<td>5.9</td>
<td>Predispense Authorization (PDA) Rejection</td>
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<td>6.1</td>
<td>Change Password</td>
<td>35</td>
</tr>
<tr>
<td>6.2</td>
<td>Change Username</td>
<td>36</td>
</tr>
<tr>
<td>6.3</td>
<td>Edit Prescriber Profile</td>
<td>37</td>
</tr>
</tbody>
</table>
1. **General Pages**

1.1 **Home Page**
1.2 Prescriber Landing Page

Prescriber Certification

Prescribers must be certified in the SILIQ REMS Program to prescribe SILIQ.

To complete prescriber certification:

READ the SILIQ Prescribing Information, to understand the risks of
SILIQ and to learn about the SILIQ REMS Program
COMPLETE a SILIQ REMS Program Prescriber Enrollment Form

To complete enrollment for SILIQ patients:

EDUCATE & COUNSEL all patients about the risks of SILIQ and how to monitor them
SIGN a SILIQ REMS Program Patient-Prescriber Agreement Form for each new
patient before prescribing SILIQ and submit the completed form to the SILIQ REMS
Program and store a copy in the patient's records

Start Prescriber Certification

Email: Siliq@SILIQREMS.com
Phone: 805-511-6156
Fax: 805-227-5451
1.3 Pharmacy Landing Page

Pharmacy Certification

All pharmacies must certify in the SILIQ REMS Program to purchase and dispense SILIQ.

To become certified, pharmacies must designate an authorized representative to complete certification. In general an authorized representative for a pharmacy:

- Coordinates the activities required for the pharmacy in the SILIQ REMS Program
- Establishes and implements processes and procedures to ensure compliance with the safe use conditions of the SILIQ REMS Program

The authorized representative for each pharmacy must complete the following steps to certify in the SILIQ REMS Program:

READ the SILIQ Prescribing Information to understand the risks of SILIQ and to learn about the SILIQ REMS Program

CERTIFY by completing and submitting the SILIQ REMS Program Pharmacy Enrollment Form

Materials for Pharmacies

- SILIQ REMS Program Pharmacy Enrollment Form
- SILIQ Prescribing Information

Start Pharmacy Certification
1.4 Patient Landing Page

Patient's Role in the SILIQ REMS Program:

Only patients who are enrolled and counseled on the safe use of SILIQ by their prescriber should be prescribed SILIQ. Patients will be counseled on the SILIQ REMS Program by certified prescribers. Patients will have the opportunity to discuss any questions or concerns they have with their prescriber. The prescriber will provide and review the SILIQ REMS Program Patient-Prescriber Agreement Form.
1.5 Coming Soon Page

Coming Soon!

The SILIQ REMS Program website is currently under construction. Please check back soon for program updates.

What is the SILIQ REMS Program?

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product, and is required by the FDA to ensure the benefits of a drug outweigh its risks.

The goal of the SILIQ REMS Program is to mitigate the observed risk of suicidal ideation and behavior, including completed suicides, which occurred in subjects treated with SILIQ by:

- Ensuring that prescribers are educated about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to counsel patients about this risk.
- Ensuring that patients are informed about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to seek medical attention for manifestations of suicidal thoughts and behavior, new onset or worsening depression, anxiety, or other mood changes.
1.6 Site Map

- Prescribers
- Pharmacies
- Patients

**Site Map**

**Prescriber**
- Prescriber Certification

**Pharmacy**
- Pharmacy Certification

**Patient**
- Patient Information

**General**
- Contact Us
- Prescribing Information
- Privacy
- Terms of Use

**Account**
- Forgot Password
- Forgot Username
- Need an Account

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451
1.7 Account Registration Page

Create an Account

To create your web account for the SILIQ REMS Program, please complete the fields below. The Username you specify must be unique within the SILIQ REMS Program website. Once you have submitted this form successfully, you will be logged in on the website. All fields below are required unless otherwise indicated.

First Name
Last Name
Email Address
Confirm Email Address
Phone Number
Username

☐ Use Email Address as Username

Password
Confirm Password

☐ I'm not a robot

Submit
Cancel
1.8 Certified Pharmacies

SILIQ Certified Pharmacy Network

The SILIQ REMS Certified Pharmacy Network list includes specialty pharmacies that are contracted to fill prescriptions for restricted distribution programs for SILIQ. All pharmacies listed are certified to dispense SILIQ.

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Certification ID</th>
<th>Pharmacy Address</th>
<th>Pharmacy Phone</th>
<th>Pharmacy Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upjohn Drugs</td>
<td>FAC-396478655</td>
<td>5228 N Rocke Drive DURHAM North Carolina 27704</td>
<td>919-333-7335</td>
<td>555-555-5555</td>
</tr>
</tbody>
</table>

Showing 1 to 2 of 2 entries
1.9  Forgot Username

Forgot Username

Please enter your credentials in the spaces provided below. Your username will be sent to the email you registered with the SILIQ REMS Program.

First Name
Last Name
Email Address

Submit
1.10 Forgot Password

Please enter your username and email address in the spaces provided below. Your username is the identification you established when creating your web account for the SILIQ REMS Program.

Username

Email Address

Submit

Email: Siliq@SILIQREMS.com
Phone: 855-511-6136
Fax: 866-227-9451
1.11 Contact Us

If you have any questions or require additional information, please contact the SILIQ REMS Program utilizing the information provided below.

Phone Number
855-511-6135

Fax Number
866-227-0451

Email Address
Siliq@SILIQREMS.com

Mailing Address
SILIQ REMS Program
PO Box XXXX
XXXXX, XX XXXXX

Program Manufacturer
Valeant Pharmaceuticals North America LLC
2. Prescriber Online Certification

2.1 Prescriber Information Page

Prescriber Intake
To certify as a prescriber in the SILIQ REMS Program, please complete the required fields below and press Next. Once certified, you will receive a certification confirmation via your preferred method of communication. All fields listed below are required unless otherwise indicated.

Prescriber Information

- First Name
- Last Name
- Email Address
- Degree
- Specialty
- Name of Institution/Healthcare Facility
- Street Address
- City
- State
- Zip Code
- Office Phone Number
- Mobile Phone Number (Optional)
- Office Fax Number
- Preferred Method of Communication

Prescriber Identifiers

- NPI Number
- DEA Number (optional)

Cancel  Next
2.2 Prescriber Attestation Page

Prescriber Attestation

To complete the prescriber certification for John Smith into the SILIQ REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrolment form using the print icon to the right and fax it to the SILIQ REMS Program at 866-227-9451.

As a prescriber, I attest that:

1. I have read and understand the SILIQ Prescribing Information.
2. I understand that I must comply with the Program requirements in order to prescribe SILIQ.
3. I understand that by signing this SILIQ REMS Program Prescriber Enrolment Form (one time only), I will be enrolled in the SILIQ REMS Program and may prescribe SILIQ.
4. I understand that, prior to authorizing the first prescription, I am responsible for counseling each patient that suicidal ideation and behavior (SIB), including completed suicides, have occurred in patients treated with SILIQ. I will inform the patient of the following key safety information:
   - Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.
   - To be aware of symptoms of suicidal ideation and behavior (SIB) events and steps to take if SIB symptoms occur.
5. I understand that I must submit a completed SILIQ REMS Program Patient-Prescriber Agreement Form for each patient before I prescribe SILIQ for the first time, and store a copy of the completed form in the patient's record.
6. I will provide each patient with a SILIQ REMS Program Patient Wallet Card and instruct each patient to carry this card with them at all times.
7. I understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.
8. I will inform the SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under my care.
9. I understand Valeant and its agents may contact me via phone, mail, fax, email, or in person to support administration of the SILIQ REMS Program.

☐ By checking this box, I agree to comply with the SILIQ REMS Program requirements.

Signature

Signature Date

Back Submit
2.3 Prescriber Confirmation Page

### Pharmacy Certification Confirmation

- **Your pharmacy is now certified in the SILIQ REMS Program**

Below is your SILIQ REMS Program Certification ID. Please retain this information for your records.

**Certification ID:** FAC123456789

To add additional pharmacies or manage your pharmacies, please use the **My Dashboard** button at the top of the page.
3. Pharmacy Online Certification

3.1 Authorized Representative Information Page

Authorized Representative Intake

To begin the process as an authorized representative in the SILIQ REMS Program, please complete the required fields below and press Next. All fields listed below are required unless otherwise indicated.

Authorized Pharmacy Representative Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td></td>
</tr>
<tr>
<td>Confirm Email Address</td>
<td></td>
</tr>
<tr>
<td>Telephone Number</td>
<td></td>
</tr>
<tr>
<td>Alternate Telephone Number</td>
<td>(Optional)</td>
</tr>
<tr>
<td>Office Fax</td>
<td></td>
</tr>
<tr>
<td>Preferred Method of Communication</td>
<td>-- Please Select --</td>
</tr>
</tbody>
</table>

[Next] [Cancel]
3.2 Authorized Representative Confirmation Page

Authorized Representative Confirmation

You are now an authorized representative in the SILIQ REMS Program.

If you are ready to certify your pharmacy now please use Certify Pharmacy. To return to your dashboard for other activities, please use the My Dashboard button at the top of the page. If you have completed your session today, simply close your browser.
### 3.3 Pharmacy Information Page

**Pharmacy Intake**

To certify your pharmacy, please complete the required fields below and press Next. Once certified, you will receive a certification confirmation via the contact preference you selected during your authorized representative intake. All fields listed below are required unless otherwise indicated.

**Pharmacy Information**

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Name</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Type</td>
<td>-- Please Select --</td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td>-- Please Select --</td>
</tr>
<tr>
<td>Zip Code</td>
<td></td>
</tr>
</tbody>
</table>

**Pharmacy Identifiers**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA Number</td>
<td></td>
</tr>
<tr>
<td>NPI Number</td>
<td></td>
</tr>
<tr>
<td>NCPDP Number</td>
<td></td>
</tr>
</tbody>
</table>

---

[Return to the top of the page]
3.4 Pharmacy Attestation Page

Pharmacy Attestation

To complete the Pharmacy Certification for **ABC Pharmacy** into the SILIQ REMS Program, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print this form by clicking on the print icon on the right and fax it to the SILIQ REMS Program at 866-227-9451.

---

I am the authorized representative designated by my pharmacy to coordinate the activities of the SILIQ REMS Program. By signing this form, I agree, on behalf of myself and my pharmacy, to comply with the following program requirements:

1. I understand that by signing this form, and upon certification from the SILIQ REMS Program, this pharmacy will be enrolled in the SILIQ REMS Program, and will be able to order and dispense SILIQ.
2. This pharmacy will re-enroll in the SILIQ REMS Program if the name and contact information for the Authorized Pharmacy Representative(s) changes.
3. This pharmacy will ensure that all relevant staff involved in the dispensing of SILIQ is trained on the SILIQ REMS Program requirements.
4. This pharmacy will maintain and make available appropriate documentation reflecting that all processes and procedures are in place and being followed.
5. I understand that non-compliance with the requirements of the SILIQ REMS Program will result in decertification of my pharmacy and termination of authorization to dispense SILIQ.
6. I will ensure that, prior to dispensing SILIQ, my pharmacy will verify that the prescriber is certified and the patient is enrolled to receive SILIQ by contacting the SILIQ REMS Program.
7. This pharmacy will comply with audits by Valeant, the U.S. Food and Drug Administration (FDA), or a designated third party acting on behalf of Valeant or FDA to ensure compliance with the SILIQ REMS Program.

By checking this box, I agree, on behalf of myself and my pharmacy, to comply with the SILIQ REMS Program requirements.

Signature: [signature]  
Signature Date: [signature date]

[Submit]  [Back]
3.5 Pharmacy Confirmation Page

Pharmacy Certification Confirmation

- Your pharmacy is now certified in the SILIQ REMS Program

Below is your SILIQ REMS Program Certification ID. Please retain this information for your records.

Certification ID: FAC123456789

To add additional pharmacies or manage your pharmacies, please use the My Dashboard button at the top of the page.
4. Patient Online Enrollment

4.1 Patient Information Page

Patient Intake
To enroll your patient into the SILIQ REMS Program, please complete the required fields below and press Next. Once the patient enrollment is complete, you will receive an enrollment confirmation via fax.

Patient Information (all fields required)

First Name
Last Name
Date of Birth
Phone Number
State
Zip Code

By signing this form, I acknowledge that:

☐ I understand that suicidal thoughts and behavior, including completed suicides, have occurred in patients treated with SILIQ.

☐ I will call my doctor or the National Suicide Prevention Lifeline at 1-800-273-8255 if:
  • I feel new or worsening feelings of withdrawal, depression, anxiety, hopelessness, or other mood changes beginning.
  • I am thinking about hurting or killing myself; seeking access to firearms, pills or other means for the purpose of self-harm; or am talking or writing about death and dying.

☐ I will call 911 if I feel an immediate threat of death or self-injury.

☐ My doctor has given me a SILIQ REMS Program Patient Wallet Card to carry with me at all times.

Patient Signature
Signature Date

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451
4.2 Prescriber Acknowledgment Page

Prescriber Acknowledgement

I acknowledge that prior to prescribing SILIQ:

☐ I have counseled my patient about the importance of seeking medical advice should signs of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes emerge.

☐ I have evaluated the risks and benefits of continuing treatment with SILIQ if such events occur.

Prescriber Signature: 

Signature Date: 

Back  Submit
4.3 Patient Enrollment Confirmation Page

Patient Enrollment Confirmation

Your patient is now enrolled in the SILIQ REMS Program.

Please print this information and tear off the bottom portion of the printed SILIQ REMS Program Patient-Prescriber Agreement Form and provide it to your patient to take home as a reference. You are responsible to retain this information for your records.

Enrollment ID: PAT123456789 📞

Email: Siliq@SILIQUERMS.com
Phone: 855-511-5135
Fax: 866-227-9451
5. Dashboard

5.1 Prescriber Dashboard

Please search for your patient in the table below and take the appropriate action. If you need to add a new patient to your list, please use the Add Patient button. For taking actions, use the Actions list.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>DOB</th>
<th>Enrollment ID</th>
<th>Enrollment Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joe</td>
<td>Doe</td>
<td>04/16/1987</td>
<td>PAT123456789</td>
<td>Enrolled</td>
<td>Please Select</td>
</tr>
<tr>
<td>John</td>
<td>Smith</td>
<td>01/01/1964</td>
<td>PAT123432145</td>
<td>Enrolled</td>
<td>Please Select</td>
</tr>
</tbody>
</table>

Email: Silq@SiliqREMS.com
Phone: 855-511-8135
Fax: 866-227-9431
5.2 Manage Patient Status

Manage Patient Status

Updating the patient status will deactivate the patient from the SILIQ REMS Program. The patient will no longer be eligible to receive SILIQ. The patient will no longer appear on the prescriber dashboard. To continue please select an option below and press Submit.

First Name: John
Last Name: Smith
Date of Birth: 02/02/1954
Zip Code: 10001
Update Patient Status: -- Please Select --

Cancel       Submit
5.3 View Patient Profile

Patient Profile

Patient Information

First Name: John
Last Name: Smith
Date of Birth: 09/02/1982
Phone: 555-555-0011
State: New York
Zip Code: 10001

Patient Enrollment Information

Enrollment ID: PAT123456789

Save
Cancel
5.4 Pharmacy Dashboard

Please search for your pharmacy in the table below and take the appropriate action. If you need to add a new pharmacy to your list, please use the Add Pharmacy button. For taking actions, use the Actions list.

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Address</th>
<th>Pharmacy Type</th>
<th>Certification ID</th>
<th>Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Pharmacy</td>
<td>1234 West Pharmacy Lane Phoenix AZ 85008</td>
<td>Inpatient</td>
<td>FAC1060000008</td>
<td>Certified</td>
<td>Please Select</td>
</tr>
<tr>
<td>XYZ Pharmacy</td>
<td>15 East Prescription Street Phoenix AZ 85008</td>
<td>Outpatient</td>
<td>FAC1060000001</td>
<td>Certified</td>
<td>Please Select</td>
</tr>
</tbody>
</table>

Showing 1 to 2 of 2 entries
5.5 Edit Authorized Pharmacy Representative Profile

My Profile

My Information

- **First Name**: John
- **Last Name**: Doe
- **Email Address**: johndoe@email.com
- **Telephone Number**: 505-555-5055
- **Alternate Telephone Number (Optional)**: 555-555-4444
- **Office Fax**: 555-555-0000
- **Preferred Method of Communication**: Email

[Edit]
5.6 View Pharmacy Profile

![Pharmacy Profile](image)

### Pharmacy Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Name</td>
<td>Pharmacy ABC</td>
</tr>
<tr>
<td>Pharmacy Type</td>
<td>Inpatient Pharmacy</td>
</tr>
<tr>
<td>Address</td>
<td>1 Main Street</td>
</tr>
<tr>
<td>City</td>
<td>New York</td>
</tr>
<tr>
<td>State</td>
<td>New York</td>
</tr>
<tr>
<td>Zip Code</td>
<td>10001</td>
</tr>
</tbody>
</table>

### Pharmacy Identifiers

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA Number</td>
<td>A023423412</td>
</tr>
<tr>
<td>NPI Number</td>
<td>23423423423</td>
</tr>
<tr>
<td>NCPDP Number</td>
<td>123546879</td>
</tr>
</tbody>
</table>

### Pharmacy Certification

Certification ID: **FAC123456789**

[Image of certification icon]

[Buttons: Cancel, Save]
5.7 Predispense Authorization (PDA) Intake

Predispense Authorization

To determine if the safe use conditions have been met to receive SILIQ, please complete the Predispense Authorization information below and Submit. The results of the Predispense Authorization will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

**Patient Information**

- First Name
- Last Name
- Date of Birth: MM/DD/YYYY
- Zip Code

**Predispense Authorization Request**

- Date of Service: MM/DD/YYYY
- NDC Number: -- Please Select --
- Days Supply
- Quantity

**Prescriber Identifiers** *(at least one identifier is required)*

- Prescriber NPI Number
- Prescriber DEA Number

[Submit] [Cancel]
5.8 Predispose Authorization (PDA) Confirmation

Predispose Authorization Result

☑ This Predispose Authorization Request has been Approved

Authorization Number: AUTH-1234-5678-9100

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451
5.9  Predispense Authorization (PDA) Rejection

Do NOT dispense SILIQ.

Reject Reason:

Please call the SILIQ REMS Program at 855-511-6135 for more information.

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451
6. Account

6.1 Change Password

Change Password
To change your password, please complete fields below.

Current Password
New Password
Confirm New Password

Cancel  Save
6.2 Change Username

To change your username, please provide your new username below. The information you provide for your username must be unique within the SILIQ REMS Program Website:

Username

- Use Email Address as Username
- Suggest Username

[Save] [Cancel]
6.3 Edit Prescriber Profile

My Profile

My Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>John</td>
</tr>
<tr>
<td>Last Name</td>
<td>Doe</td>
</tr>
<tr>
<td>Email Address</td>
<td><a href="mailto:john.doe@email.com">john.doe@email.com</a></td>
</tr>
<tr>
<td>Degree</td>
<td>MD</td>
</tr>
<tr>
<td>Specialty</td>
<td>General</td>
</tr>
<tr>
<td>Name of Institution/Healthcare Facility</td>
<td>Good Health Clinic</td>
</tr>
<tr>
<td>Street Address</td>
<td>1 Main Street</td>
</tr>
<tr>
<td>City</td>
<td>New York</td>
</tr>
<tr>
<td>State</td>
<td>New York</td>
</tr>
<tr>
<td>Zip Code</td>
<td>10001</td>
</tr>
<tr>
<td>Office Phone Number</td>
<td>555-555-5555</td>
</tr>
<tr>
<td>Mobile Phone Number (Optional)</td>
<td>555-555-5111</td>
</tr>
<tr>
<td>Office Fax Number</td>
<td>555-555-0000</td>
</tr>
<tr>
<td>Preferred Method of Communication</td>
<td>Email</td>
</tr>
</tbody>
</table>

Prescriber Identifiers

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA Number (Optional)</td>
<td>AB323423412</td>
</tr>
<tr>
<td>NPI Number</td>
<td>23423423423</td>
</tr>
</tbody>
</table>

My Certification

Certification ID: HCP123546789

[Submit Button]
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KENDALL A MARCUS
02/15/2017