

Initial REMS approval: 08/2015

NDA 22526 Addyi™ (flibanserin)

Serotonin 1A receptor agonist and a Serotonin 2A receptor antagonist

Sprout Pharmaceuticals, Inc.

4208 Six Forks Road, Suite 1010

Raleigh, NC 27609

Phone: 919-882-0850

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(s)

The goal of the Addyi REMS is to mitigate the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol by:

- Ensuring prescribers and pharmacists are educated about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol and the need to counsel patients about this risk.
- Informing patients of the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

II. ELEMENTS

A. Elements To Assure Safe Use

1. Healthcare providers who prescribe Addyi for outpatient use must be specially certified.
 - a. To become specially certified to prescribe Addyi in the Addyi REMS Program, healthcare providers must:
 - i. Review the Prescribing Information (PI) for Addyi.
 - ii. Review the *Addyi REMS Program Prescriber and Pharmacy Training* and successfully complete the *Addyi REMS Program Knowledge Assessment*.
 - iii. Enroll in the Addyi REMS Program by completing the *Addyi REMS Program Prescriber Enrollment Form*.
 - b. As a condition of certification, prescribers must:
 - i. Counsel patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol, using the *Addyi REMS Program Patient-Provider*

Agreement Form. Maintain the completed *Addyi REMS Program Patient-Provider Agreement Form* in the patient's records and provide the patient with the portion of the *Addyi REMS Program Patient-Provider Agreement* designated for patient receipt.

- ii. Report any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals.
- c. Sprout Pharmaceuticals must:
 - i. Ensure that healthcare providers who prescribe Addyi for outpatient use are specially certified, in accordance with the requirements described above.
 - ii. Ensure that healthcare providers can complete the enrollment and certification processes in the Addyi REMS Program online, by email, by fax, or by phone..
 - iii. Ensure that healthcare providers are notified when they have been certified in the Addyi REMS Program.
 - iv. Maintain a validated, secure database of healthcare providers who are certified to prescribe Addyi in the Addyi REMS Program.
 - v. Ensure that healthcare providers meet the REMS requirements and de-certify healthcare providers who do not maintain compliance with REMS requirements.
 - vi. Ensure that certified prescribers are provided access to the database of certified pharmacies.
 - vii. Provide the *Addyi REMS Program Prescriber Enrollment Form*, *Addyi REMS Program Prescriber and Pharmacy Training*, *Addyi REMS Program Knowledge Assessment*, and the PI to healthcare providers who (1) attempt to prescribe Addyi and are not yet certified, or (2) inquire about how to become certified.

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

- [*Addyi REMS Program Prescriber Enrollment Form*](#)
- [*Addyi REMS Program Prescriber and Pharmacy Training*](#)
- [*Addyi REMS Program Knowledge Assessment*](#)
- [*Addyi REMS Program Website screenshots*](#)
- [*Addyi REMS Program Patient-Provider Agreement Form*](#)

2. Pharmacies that dispense Addyi must be specially certified.

- a. To become specially certified to dispense Addyi in the Addyi REMS Program, pharmacies must:
 - i. Designate an authorized representative to complete the enrollment and certification processes by submitting the completed appropriate pharmacy enrollment form on behalf of the pharmacy.
 - 1) Outpatient Pharmacy:
 - *Addyi REMS Program Multiple Location Pharmacy Enrollment Form*

- *Addyi REMS Program Individual Location Pharmacy Enrollment Form*

- 2) Inpatient Pharmacy: *Addyi REMS Program Inpatient Pharmacy Enrollment Form*
- ii. Ensure that the authorized representative oversees implementation and compliance with the Addyi REMS Program requirements by doing the following:
 - 1) Review the *Addyi REMS Program Prescriber and Pharmacy Training* and the PI and successfully complete the *Addyi REMS Program Knowledge Assessment*.
 - 2) Ensure all relevant staff involved in the dispensing of Addyi are trained on the Addyi REMS Program requirements using the *Addyi REMS Program Prescriber and Pharmacy Training* and maintain a record of training.
 - 3) Put processes and procedures in place to ensure that prior to dispensing Addyi, the outpatient pharmacy verifies the prescriber is certified in the Addyi REMS Program and counsels the patient to avoid alcohol use with Addyi.
 - 4) Ensure all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals or MedWatch.
 - 5) Maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide such documentation upon request to Sprout Pharmaceuticals, FDA, or a designated third party.
 - 6) Comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
 - b. As a condition of certification:
 - i. Outpatient pharmacies:
 - 1) Must recertify in the Addyi REMS Program if the pharmacy designates a new authorized representative.
 - 2) A pharmacy that supports electronic communication verification with the Addyi REMS Program system must:
 - a) Ensure the pharmacy enables its pharmacy management system to support communication with the Addyi REMS Program system, using established telecommunication standards, and runs the standardized validation test transaction to validate the system enhancements.
 - b) Dispense Addyi to patients only after obtaining a predispose authorization (PDA) by processing each prescription through its pharmacy management system to electronically verify the prescriber is certified in the Addyi REMS Program.
 - c) Prior to dispensing, counsel patients to avoid alcohol use with Addyi. .
 - 3) A pharmacy that does NOT support electronic telecommunication verification with the Addyi REMS Program system must:

- a) Dispense Addyi to patients only after obtaining authorization by calling the REMS Program Support Center to verify the prescriber is certified in the Addyi REMS Program.
 - b) Prior to dispensing, counsel patients to avoid alcohol use with Addyi.
- ii. Inpatient Pharmacies must:
 - 1) Recertify in the Addyi REMS Program if the pharmacy designates a new authorized representative.
 - 2) Dispense Addyi only for inpatient use unless the pharmacy is enrolled as an outpatient pharmacy and can comply with the requirements under 2(b)(i).
- c. Sprout Pharmaceuticals must:
 - i. Ensure that pharmacies that dispense Addyi are specially certified, in accordance with the requirements described above.
 - ii. Ensure that pharmacies can complete the certification and enrollment processes in the Addyi REMS Program online, by email, by fax, or by phone.
 - iii. Ensure that pharmacies are notified when they have been certified by the Addyi REMS Program.
 - iv. Verify every 2 years that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy. If different, the pharmacy will be required to re-certify with a new authorized representative.

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

- *Addyi REMS Program Multiple Location Pharmacy Enrollment Form*
- *Addyi REMS Program Individual Location Pharmacy Enrollment Form*
- *Addyi REMS Program Inpatient Pharmacy Enrollment Form*
- *Addyi REMS Program Prescriber and Pharmacy Training*
- *Addyi REMS Program Knowledge Assessment*

B. Implementation System

- 1. Sprout Pharmaceuticals must ensure that Addyi is only distributed to certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute Addyi comply with the program requirements for wholesalers/distributors. The authorized wholesalers/distributors must:

- i. Put processes and procedures in place to verify, prior to distributing Addyi, that the pharmacy is certified using the validated, secure database provided by the Addyi REMS Program.
 - ii. Train all relevant staff on the Addyi REMS Program requirements.
 - iii. Comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program. In addition, wholesalers/distributors must maintain appropriate documentation and make it available for audits.
 - iv. Provide distribution data to Sprout Pharmaceuticals.
 - b. Ensuring that authorized wholesalers/distributors maintain distribution records of all shipments of Addyi and provide the data to Sprout Pharmaceuticals.
2. Sprout Pharmaceuticals must audit the wholesalers/distributors within 60 calendar days after each wholesaler/distributor is authorized to distribute Addyi in order to ensure that all processes and procedures are in place and functioning to support the requirements of the Addyi REMS Program. Sprout Pharmaceuticals must ensure the authorized wholesalers/distributors meet the REMS requirements and institute corrective action for wholesalers/distributors who do not maintain compliance with the REMS requirements.
 3. Sprout Pharmaceuticals must maintain a validated, secure database of pharmacies that are certified to dispense Addyi in the Addyi REMS Program.
 4. Sprout Pharmaceuticals must maintain records of Addyi distribution and dispensing, certified prescribers, certified pharmacies, and authorized wholesalers/distributors to meet the REMS requirements.
 5. Sprout Pharmaceuticals must ensure that the pharmacies and authorized wholesalers/distributors meet the REMS requirements and will de-certify pharmacies and authorized wholesalers/distributors who do not maintain compliance with the REMS requirements.
 6. Sprout Pharmaceuticals must maintain an Addyi REMS Support Center (1-844-233-9415) and Addyi REMS Program Website (www.AddyiREMS.com). The REMS Program Website must include the option to print the PI, Medication Guide, and Addyi REMS materials. The Addyi product website for consumers and healthcare providers (www.Addyi.com) must include a prominent REMS-specific link to the Addyi REMS Program Website.
 7. Sprout Pharmaceuticals must ensure that within 30 calendar days of REMS approval the REMS materials listed in or appended to the Addyi REMS document are available through the Addyi REMS Program Website or by calling the Addyi REMS Support Center.
 8. Sprout Pharmaceuticals must monitor the certified pharmacies to ensure the requirements of the Addyi REMS Program are being met. Sprout Pharmaceuticals must institute corrective action if noncompliance is identified.
 9. Sprout Pharmaceuticals must audit 100 certified pharmacies or 1% of certified pharmacies, whichever is greater, within 180 calendar days after the pharmacy places its first order of Addyi to ensure that all processes and procedures are in place and functioning to support the requirements of the Addyi

REMS Program. The certified pharmacies will also be included in Sprout Pharmaceuticals' ongoing annual audit plan. Sprout Pharmaceuticals must institute corrective action for certified pharmacies who do not maintain compliance with the REMS requirements.

10. Sprout Pharmaceuticals must take reasonable steps to improve implementation of and compliance with the requirements in the Addyi REMS Program based on monitoring and evaluation of the Addyi REMS Program.

III. Timetable for Submission of Assessments

Sprout Pharmaceuticals must ensure FDA receives REMS assessments 6 months and 12 months from the date of the initial approval of the REMS (August 18, 2015) and annually thereafter on or before the anniversary date of the initial REMS approval. 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 assessment due date.

APPENDIX A: ADDYI REMS PROGRAM PRESCRIBER ENROLLMENT FORM

AddyiTM REMS Program Prescriber Enrollment Form

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for AddyiTM (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. Addyi is only available from prescribers and pharmacies that have been certified through the Addyi REMS Program.

Completing prescriber certification can either be done online at www.AddyiREMS.com or by reviewing a hard copy of the *Addyi REMS Program Prescriber and Pharmacy Training Program*, completing the *Addyi REMS Program Knowledge Assessment*, and submitting this Enrollment Form. If you've received a hard copy of the *Addyi REMS Program Prescriber and Pharmacy Training Program*, successfully completing the prescriber certification process requires you to:

1. Read the Addyi Prescribing Information and *Addyi REMS Program Prescriber and Pharmacy Training Program*.
2. Review your knowledge and successfully complete the *Addyi REMS Program Knowledge Assessment*.
3. Enroll by completing the *Addyi REMS Program Knowledge Assessment* and this one-time *Addyi REMS Program Prescriber Enrollment Form* (all fields must be completed). This may be:
 - a. Faxed to the Addyi REMS Program Support Center at 1-844-694-3373 or
 - b. Scanned and e-mailed to AddyiREMS@AddyiREMS.com

Prescriber Attestations:

1. I understand that Addyi is only available through prescribers and pharmacies that are certified by the Addyi REMS Program and that I must comply with the program requirements to prescribe Addyi.
2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
3. I have reviewed the Addyi Prescribing Information.
4. I have reviewed the *Addyi REMS Program Prescriber and Pharmacy Training Program* and successfully completed the *Addyi REMS Program Knowledge Assessment*.
5. I will counsel my patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol, using the *Addyi REMS Program Patient-Provider Agreement Form*.
6. I will maintain the completed *Addyi REMS Program Patient-Provider Agreement Form* in the patient's records and provide the patient with the portion of the *Patient-Provider Agreement* designated for patient receipt.
7. I understand that the Addyi REMS Program may contact me via phone, mail, or email to survey me on the effectiveness of the REMS Program requirements.
8. I will report any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals at 1-844-746-5745.

Prescriber's Signature

Date

Print Name

NPI #

DEA#

Please Complete the Following Page

AddyiTM REMS Program Prescriber Enrollment Form

First Name: _____

Last Name: _____

Practice Name: _____

Street Address: _____

City: _____

ST: _____

Zip: _____

Are you a: MD ☐ DO ☐ PA ☐ NP ☐ Other _____

Clinical Specialty: Gynecology ☐ Family Medicine ☐ Internal Medicine ☐ Psychiatry ☐ Other _____

NPI#: _____

DEA # (optional): _____

Telephone #: _____

Fax #: _____

E-mail: _____

Confirm E-mail: _____

Preferred Method of Communication (please select one): ☐ Fax ☐ Email

If manually completing, please fax all pages of this form to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. Ensure your completed Knowledge Assessment and Enrollment Form is provided to the Addyi REMS Program Support Center.

APPENDIX B: ADDYI REMS PROGRAM PRESCRIBER AND PHARMACY TRAINING



AddyiTM REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Sprout Pharmaceuticals, Inc.
4208 Six Forks Rd, Suite 1010
Raleigh, NC 27609

Addyi™ REMS Program Overview

- The Food and Drug Administration (FDA) has required a **Risk Evaluation and Mitigation Strategy (REMS)** to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.
- Prescribers and Pharmacies **must be certified** in the Addyi REMS program to prescribe and dispense Addyi.
- Outpatient Pharmacies will only fill an Addyi prescription written by a certified prescriber. This is verified electronically when each Addyi prescription is processed through the pharmacy's computer system or by calling the Addyi REMS Program Support Center.

Addyi™ REMS Program Prescriber and Pharmacy Training

- The information presented in this training program does not include a complete list of all risks and safety information on Addyi.
- Before prescribing or dispensing Addyi, please read the Addyi Prescribing Information and the Addyi Medication Guide available at www.AddyiREMS.com.
- Further information is also available at www.AddyiREMS.com.

Addyi™ REMS Program Certification Process

Complete the Addyi REMS Program Prescriber and Pharmacy Training in 3 easy steps*:

READ

Read the Addyi REMS Program Prescriber and Pharmacy Training and Prescribing Information

REVIEW

Review your knowledge by answering Knowledge Assessment questions

ENROLL

Enroll by completing the enrollment process online or by faxing the appropriate enrollment form

*For online enrollment first sign-up by creating an account and providing all requested contact information

Addyi™ REMS Goal

The goal of the Addyi REMS is to mitigate the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol by:

- Ensuring prescribers and pharmacists are educated about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol and the need to counsel patients about this risk.
- Informing patients of the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

Addyi™ is Indicated for HSDD

- Addyi is indicated for the treatment of premenopausal women with acquired generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
 - A co-existing medical or psychiatric condition,
 - Problems within the relationship, or
 - The effects of a medication or other drug substance.

Limitations of Use

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.

Addyi™ and Alcohol: Increased Risk of Hypotension and Syncope

- Dedicated alcohol interaction study with Addyi in 23 men and 2 premenopausal women.
- All subjects were co-administered Addyi 100 mg and the equivalent of two or four glasses of wine* consumed over 10 minutes in the morning.
- Severe hypotension was observed.
- Therapeutic intervention was needed in some cases.
- There were no events requiring therapeutic intervention when Addyi or alcohol was administered alone.

*Each glass of wine containing 12% alcohol content = one can of beer containing 5% alcohol = 1.5 ounce shot of 80-proof spirit in a 70 kg person

Addyi™ and Alcohol:

Increased Risk of Hypotension and Syncope

- Four of 23 subjects (17%) co-administered Addyi 100 mg and the equivalent of two glasses of wine had events of hypotension or syncope.
 - Systolic blood pressure reductions from 28 to 54 mmHg
 - Diastolic blood pressure reductions from 24 to 46 mmHg
- Six of the 24 subjects (25%) co-administered Addyi 100 mg and the equivalent of four glasses of wine experienced orthostatic hypotension when standing from a sitting position
 - Systolic blood pressure reductions from 22 to 48 mmHg
 - Diastolic blood pressure reductions from 0 to 27 mmHg

Addyi™ Contraindications

- **Alcohol**
- Moderate or strong CYP3A4 inhibitors
- Hepatic impairment

Addyi™ and Alcohol

- Patients must not take Addyi unless they can abstain from alcohol use for the full duration of treatment.
- Prescribers need to evaluate a patient's ability to abstain from using alcohol.
- Prescribers and Pharmacists must counsel their patients on the increased risk of hypotension and syncope with Addyi due to an interaction with alcohol and the need to abstain from alcohol.
- The **Addyi REMS Patient-Provider Agreement Form** is an important tool for healthcare providers to use with patients.

Addyi™ REMS Program Patient-Provider Agreement

- The **Addyi REMS Program Patient-Provider Agreement Form** must be used to counsel patients upon receiving their initial prescription for Addyi.
- After signing, this form should be kept in the patient's chart.
- The bottom portion can be torn off for the patient to take home.
- **This form may also be used for pharmacy counseling.**

Addyi™ REMS Program Patient-Provider Agreement Form

Healthcare Provider:

- Alcohol use is contraindicated in women taking Addyi™ (flibanserin).
- Addyi and alcohol interact and increase the risk of severe hypotension and syncope.
- I agree to:
 - Use this Patient Provider Agreement Form to counsel my patients about these risks and the importance of abstaining from alcohol.
 - Sign this form along with my patient and place a copy in her chart.
 - **Tear off** the bottom portion and provide it to my patient to take home for her reference.

Prescriber Signature _____ Date _____

Pharmacist: This form may be used as an optional tool for counseling patients. No charting or signatures are required.

Patient:

I understand that I must not drink alcohol while taking Addyi. Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.
- I understand the instructions that my healthcare provider has given to me.

Patient Signature _____ Date _____

tear here

addyi[™]
(flibanserin)

Addyi™ Patient Information

I understand that I must not drink alcohol while taking Addyi (flibanserin). Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

For more information about Addyi please visit www.AddyiREMS.com

©2015 Sprout Pharmaceuticals, Inc. Addyi REMS Patient-Provider Agreement

Patient-Provider Agreement: Patient Information

Patients taking Addyi™ must express an understanding of the following:

- **I understand I must not drink alcohol while taking Addyi (flibanserin).**
- Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).
- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

APPENDIX C: ADDYI REMS PROGRAM KNOWLEDGE ASSESSMENT

Addyi™ REMS Program Knowledge Assessment

Confirm Your Understanding Through Knowledge Assessment (circle your answer)

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

Why is alcohol contraindicated with Addyi?	a) Hepatotoxicity b) Teratogenicity	c) Hypotension and syncope d) Hypersensitivity
What is the purpose of the Addyi REMS Patient-Provider Agreement Form?	a) For prescribers to counsel patients at the office visit. b) For patient charting	c) For the patient to take home the important safety messages d) For pharmacy counseling e) All of the above
How often must pharmacists counsel patients about the need to avoid alcohol?	a) Never b) Only if the patient asks about alcohol use	c) With the first prescription only d) With every prescription
What is the primary counseling message for the patient?	a) Do not drink alcohol while taking Addyi until you know how alcohol affects you. b) Limit your alcohol use while taking Addyi	c) You must not drink alcohol while taking Addyi d) Do not drink alcohol at night when you take your daily Addyi

First Name:

Last Name:

NPI#

DEA#

addyi[®]
(flibanserin)

Print this page and complete Knowledge Assessment. This page, along with the appropriate enrollment form will need to be faxed to the Addyi REMS Support Center (1-844-694-3373) or print, scan and e-mail to AddyiREMSEnroll@AddyiREMS.com to complete certification.

Reference ID: 3808140

Addyi REMS Knowledge Assessment © 2015 Sprout Pharmaceuticals, Inc. Addyi REMS Program Prescriber and Pharmacy Training

APPENDIX D: ADDYI REMS PROGRAM WEBSITE SCREENSHOTS

Website Under Construction



Thank You for Visiting www.AddyiREMS.com

Click [here](#) for Prescribing Information

Click [here](#) for Indication and Important Safety Information.

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.



Risk Evaluation and Mitigation Strategy (REMS)

FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

[Prescriber Training, Enrollment, and Certification \(3 Easy Steps\)](#)

[Pharmacy Training, Enrollment, and Certification \(3 Easy Steps\)](#)

[Addyi Certified Pharmacy Network](#)

[Log In](#)

Addyi Risk Evaluation and Mitigation Strategy (REMS)

What is the Addyi REMS Program?

A 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 purpose of the Addyi REMS Program is to inform prescribers, outpatient pharmacies, inpatient pharmacies, and patients about the increased risk of:

- **Hypotension and Syncope** due to an interaction with alcohol

Addyi REMS Program Requirements

Prescribers

- To be able to prescribe Addyi, prescribers must be trained, successfully Addyi REMS Program.
- Before prescribing Addyi, prescribers must review and complete the *Addyi REMS Program Patient-Provider Agreement Form* with every patient.

Outpatient Pharmacies

- To be able to dispense Addyi, the Authorized Representative of the knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS Program.
- To be able to dispense Addyi, outpatient pharmacies must train all relevant pharmacy staff involved in dispensing.
- Before dispensing every prescription, pharmacies must counsel all patients on the need to avoid alcohol.

Inpatient Pharmacies

- To be able to dispense Addyi, the Authorized Representative of the knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS Program.
- To be able to dispense Addyi, inpatient pharmacies must train all relevant pharmacy staff involved in dispensing.
- [Inpatient Pharmacies must not dispense Addyi for outpatient use.](#)

Click on the appropriate button below to complete the certification process in 3 easy steps.



PRESCRIBERS

[Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training](#)



PHARMACIES

[Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training](#)

Materials for Prescribers

- ▶ [Addyi REMS Program Prescriber and Pharmacy Training \(Including a Knowledge Assessment\)](#)
- ▶ [Addyi REMS Program Prescriber Enrollment Form](#)
- ▶ [Addyi REMS Program Patient-Provider Agreement Form](#)
- ▶ [Prescribing Information](#)
- ▶ [Medication Guide](#)

Materials for Pharmacies

- ▶ [Addyi REMS Program Prescriber and Pharmacy Training \(Including Location Outpatient Pharmacy Enrollment Form\)](#)
- ▶ [Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form](#)
- ▶ [Addyi REMS Program Inpatient Pharmacy Enrollment Form](#)
- ▶ [Addyi REMS Program Patient-Provider Agreement Form](#)
- ▶ [Prescribing Information](#)
- ▶ [Medication Guide](#)

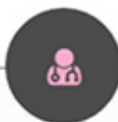
Materials for Patients

- ▶ [Addyi REMS Program Patient-Provider Agreement Form](#)
- ▶ [Medication Guide](#)

Addyi REMS Program Support Center

Hours of Operation:
 8:00 AM – 8:00 PM ET

Click on the appropriate button below to complete the certification process in 3 easy steps.



PRESCRIBERS

Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training



PHARMACIES

Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training



Indication:

Addyi is indicated for the treatment of premenopausal women with acquired generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:

- A co-existing medical or psychiatric condition,
- Problems within the relationship, or
- The effects of a medication or other drug substance.

Limitations of Use:

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.

addyiTM
(flibanserin)

Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search

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Addyi REMS Website

[Edit this page](#)

Materials for Patients

- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Medication Guide

Addyi REMS Program Support Center

🕒 **Hours of Operation:**
8:00 AM – 8:00 PM ET

✉ **Email:**
AddyiREMSsupport@AddyiREMS.com

☎ **Phone:** 1-844-233-9415

📠 **Fax:** 1-844-694-3373

Sprout Customer Service

☎ **Phone:** 1-844-746-5745



- ▶ Privacy Policy
- ▶ Contact Us
- ▶ ADDYI.com

You are encouraged to report side effects of prescription drugs to the FDA.

Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.



Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

Prescriber Training, Enrollment
and Certification (3 Easy Steps)

Pharmacy Network

Log In

Addyi Risk Evaluation and Mitigation Strategy (REMS)

What is the Addyi REMS Program?

A 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 purpose of the Addyi REMS Program is to inform prescribers, outpatient pharmacies, inpatient pharmacies, and patients about the increased risk of:

- **Hypotension and Syncope** due to an interaction with alcohol

Addyi REMS Program Requirements

Prescribers

- To be able to prescribe Addyi, prescribers must be trained, successfully Addyi REMS Program.
- Before prescribing Addyi, prescribers must review and complete the *Addyi REMS Program Patient-Provider Agreement Form* with every patient.

Outpatient Pharmacies

- To be able to dispense Addyi, the Authorized Representative of the knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS Program.
- To be able to dispense Addyi, outpatient pharmacies must train all relevant pharmacy staff involved in dispensing.
- Before dispensing every prescription, pharmacies must counsel all patients on the need to avoid alcohol.

Inpatient Pharmacies

- To be able to dispense Addyi, the Authorized Representative of the knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS Program.
- To be able to dispense Addyi, inpatient pharmacies must train all relevant pharmacy staff involved in dispensing.
- Inpatient Pharmacies must not dispense Addyi for outpatient use.

Materials for Prescribers

- ▶ Addyi REMS Program Prescriber and Pharmacy Training (Including a Knowledge Assessment)
- ▶ Addyi REMS Program Prescriber Enrollment Form
- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Prescribing Information
- ▶ Medication Guide

Materials for Pharmacies

- ▶ Addyi REMS Program Prescriber and Pharmacy Training (Including Location Outpatient Pharmacy Enrollment Form)
- ▶ Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- ▶ Addyi REMS Program Inpatient Pharmacy Enrollment Form
- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Prescribing Information
- ▶ Medication Guide

Materials for Patients

- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Medication Guide

Addyi REMS Program Support Center

Ⓢ Hours of Operation:
8:00 AM – 8:00 PM ET

Click on the appropriate button below to complete the certification process in 3 easy steps.



PRESCRIBERS

Click Here to Start the Addyi REMS
Program Prescriber and Pharmacy
Training



PHARMACIES

Click Here to Start the Addyi REMS
Program Prescriber and Pharmacy
Training



Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

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Prescriber Training, Enrollment,
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Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

Log In

Create an Account

To create your web account for the Addyi™ (flibanserin) REMS Program, please complete the fields below.

The Username you specify must be unique within the Addyi REMS Program website. All fields are required unless otherwise indicated.

First Name

Last Name

Email Address

Certification ID

Enter your certification ID if you have enrolled via fax or email. If you do not currently have a certification ID, one will be provided upon receipt of your enrollment confirmation.

Username

Suggest Username Check Username Availability

☐ Use Email Address as Username

Password

Confirm Password

Submit

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Prescriber Training, Enrollment, and Certification (3 Easy Steps)

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi™ (flibanserin) outweigh the increased risk of **hypotension and syncope** due to an interaction with alcohol.

Prescribers and Pharmacies must be certified in the Addyi REMS Program to prescribe and dispense Addyi. For prescribers to successfully become certified they must complete the following 3 easy steps*:

1. **Read** the Addyi REMS Program Prescriber and Pharmacy Training and Prescribing Information.
2. **Review** your knowledge by answering Knowledge Assessment questions.
3. **Enroll** by completing the enrollment process online or by faxing the appropriate enrollment form.

**For online enrollment first sign-up by creating an account and providing all requested contact information*

For prescribers the entire Addyi REMS Program certification process can be completed online or by downloading and following the directions in the Addyi REMS Program Prescriber and Pharmacy Training document, available on this website. You may also call the Addyi REMS Program Support Center (1-844-233-9415) to request that the requisite materials be sent to you.

PRESCRIBERS: CLICK THE BUTTON BELOW TO INITIATE THE ENTIRE ADDYI REMS PROGRAM TRAINING, ENROLLMENT AND CERTIFICATION PROCESS. COMPLETION SHOULD TAKE LESS THAN 10 MINUTES.



PRESCRIBERS

Click Here to Start the
ADDYI REMS PROGRAM TRAINING, ENROLLMENT
AND CERTIFICATION PROCESS



Materials for Prescribers

- ▶ Addyi REMS Program Prescriber and Pharmacy Training (Including a Knowledge Assessment)
- ▶ Addyi REMS Program Prescriber Enrollment Form
- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Prescribing Information
- ▶ Medication Guide

Materials for Pharmacies

- ▶ Addyi REMS Program Prescriber and Pharmacy Training (Including a Knowledge Assessment)
- ▶ Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form
- ▶ Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- ▶ Addyi REMS Program Inpatient Pharmacy Enrollment Form
- ▶ Addyi REMS Program Patient-Provider Agreement Form
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- ▶ Medication Guide

Materials for Patients

- ▶ Addyi REMS Program Patient-Provider Agreement Form
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Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search

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Addyi REMS Website

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🕒 Hours of Operation:

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✉ Email:

AddyiREMSSupport@AddyiREMS.com

📞 Phone: 1-844-233-9415

📠 Fax: 1-844-694-3373

Sprout Customer Service

📞 Phone: 1-844-746-5745



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First Name

Last Name

Email Address

Certification ID

Enter your certification ID if you have enrolled via fax or email. If you do not currently have a certification ID, one will be provided upon receipt of your enrollment confirmation.

Username

Suggest Username Check Username Availability

☐ Use Email Address as Username

Password

Confirm Password

Submit



START

Materials for Patients

► Addyi REMS Program Patient-
Provider Agreement Form

► Medication Guide



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Addyi REMS Program Prescriber Information Intake Form

Complete All Fields Below

First Name

Last Name

Telephone Number

Fax Number

Email



Preferred Method of Contact

☐ Fax ☐ Email

NPI

DEA

Professional Designation

☐ MD ☐ DO ☐ PA ☐ NP ☐ Other

Your Clinical Specialty

☐ Gynecology ☐ Internal Medicine
☐ Family Medicine ☐ Psychiatry ☐ Other

Name of Practice/Clinic

Address

City

State

Zip Code

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Addyi REMS Program Prescriber and Pharmacy Training



Addyi™ REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

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Raleigh, NC 27609

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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Overview

- The Food and Drug Administration (FDA) has required a **R**isk **E**valuation and **M**itigation **S**trategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.
- Prescribers and Pharmacies **must be certified** in the Addyi REMS program to prescribe and dispense Addyi.
- Outpatient Pharmacies will only fill an Addyi prescription written by a certified prescriber. This is verified electronically when each Addyi prescription is processed through the pharmacy's computer system or by calling the Addyi REMS Program Support Center.



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Prescriber and Pharmacy Training

- The information presented in this training program does not include a complete list of all risks and safety information on Addyi.
- Before prescribing or dispensing Addyi, please read the Addyi Prescribing Information and the Addyi Medication Guide available at www.AddyiREMS.com.
- Further information is also available at www.AddyiREMS.com.



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Certification Process

Complete the Addyi REMS Program Prescriber and Pharmacy
Training in 3 easy steps*:

READ

Read the Addyi REMS
Program Prescriber and
Pharmacy Training and
Prescribing Information

REVIEW

Review your knowledge
by answering Knowledge
Assessment questions

ENROLL

Enroll by completing
the enrollment process
online or by faxing the
appropriate enrollment
form

*For online enrollment first sign-up by creating an account and providing all requested contact information



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Goal

The goal of the Addyi REMS is to mitigate the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol by:

- Ensuring prescribers and pharmacists are educated about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol and the need to counsel patients about this risk.
- Informing patients of the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ is Indicated for HSDD

- Addyi is indicated for the treatment of premenopausal women with acquired generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
 - A co-existing medical or psychiatric condition,
 - Problems within the relationship, or
 - The effects of a medication or other drug substance.

Limitations of Use

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ and Alcohol: Increased Risk of Hypotension and Syncope

- Dedicated alcohol interaction study with Addyi in 23 men and 2 premenopausal women.
- All subjects were co-administered Addyi 100 mg and the equivalent of two or four glasses of wine* consumed over 10 minutes in the morning.
- Severe hypotension was observed.
- Therapeutic intervention was needed in some cases.
- There were no events requiring therapeutic intervention when Addyi or alcohol was administered alone.

*Each glass of wine containing 12% alcohol content = one can of beer containing 5% alcohol = 1.5 ounce shot of 80-proof spirit in a 70 kg person



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ and Alcohol: Increased Risk of Hypotension and Syncope

- Four of 23 subjects (17%) co-administered Addyi 100 mg and the equivalent of two glasses of wine had events of hypotension or syncope.
 - Systolic blood pressure reductions from 28 to 54 mmHg
 - Diastolic blood pressure reductions from 24 to 46 mmHg
- Six of the 24 subjects (25%) co-administered Addyi 100 mg and the equivalent of four glasses of wine experienced orthostatic hypotension when standing from a sitting position
 - Systolic blood pressure reductions from 22 to 48 mmHg
 - Diastolic blood pressure reductions from 0 to 27 mmHg



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ Contraindications

- **Alcohol**
- Moderate or strong CYP3A4 inhibitors
- Hepatic impairment



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ and Alcohol

- Patients must not take Addyi unless they can abstain from alcohol use for the full duration of treatment.
- Prescribers need to evaluate a patient's ability to abstain from using alcohol.
- Prescribers and Pharmacists must counsel their patients on the increased risk of hypotension and syncope with Addyi due to an interaction with alcohol and the need to abstain from alcohol.
- The **Addyi REMS Program Patient-Provider Agreement Form** is an important tool for healthcare providers to use with patients.



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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Patient-Provider Agreement

- The **Addyi REMS Program Patient-Provider Agreement Form** must be used to counsel patients upon receiving their initial prescription for Addyi.
- After signing, this form should be kept in the patient's chart.
- The bottom portion can be torn off for the patient to take home.
- **This form may also be used for pharmacy counseling.**

Addyi™ REMS Program Patient-Provider Agreement Form

Healthcare Provider:

- Alcohol use is contraindicated in women taking Addyi™ (flibanserin).
- Addyi and alcohol interact and increase the risk of severe hypotension and syncope.
- I agree to:
 - Use this Patient Provider Agreement Form to counsel my patients about these risks and the importance of abstaining from alcohol.
 - Sign this form along with my patient and place a copy in her chart.
 - Tear off the bottom portion and provide it to my patient to take home for her reference.

Prescriber Signature _____ Date _____

Pharmacist: This form may be used as an optional tool for counseling patients. No charting or signatures are required.

Patient:

I understand that I must not drink alcohol while taking Addyi. Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.
- I understand the instructions that my healthcare provider has given to me.

Patient Signature _____ Date _____

addyi™ (flibanserin) Addyi™ Patient Information

I understand that I must not drink alcohol while taking Addyi (flibanserin). Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

For more information about Addyi please visit www.AddyiREMS.com

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Addyi REMS Program Prescriber and Pharmacy Training

Patient-Provider Agreement: Patient Information

Patients taking Addyi™ must express an understanding of the following:

- **I understand I must not drink alcohol while taking Addyi (flibanserin).**
- Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).
- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.



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Addyi REMS Program Prescriber and Pharmacy Training

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

[Take the Knowledge Assessment](#)



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Addyi REMS Program Knowledge Assessment

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

1. Why is alcohol contraindicated with Addyi?

- ☐ Hepatotoxicity
- ☐ Teratogenicity
- ☐ Hypotension and syncope
- ☐ Hypersensitivity

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

- ☐ For prescribers to counsel patients at the office visit
- ☐ For patient charting
- ☐ For the patient to take home the important safety messages
- ☐ For pharmacy counseling
- ☐ All of the above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

- ☐ Never
- ☐ Only if the patient asks about alcohol use
- ☐ With the first prescription only
- ☐ With every prescription

4. What is the primary counseling message for the patient?

- ☐ Do not drink alcohol while taking Addyi until you know how alcohol affects you
- ☐ Limit your alcohol use while taking Addyi
- ☐ You must not drink alcohol while taking Addyi
- ☐ Do not drink alcohol at night when you take your daily Addyi

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Prescriber Attestations

x

Please click to attest to each of the following statements:

Attest

I understand that Addyi is only available through prescribers and pharmacies that are certified by the Addyi REMS Program and that I must comply with the program requirements to prescribe Addyi.

☐

I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

☐

I have reviewed the Addyi Prescribing Information.

☐

I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training and successfully completed the Addyi REMS Program Knowledge Assessment.

☐

I will counsel my patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol, using the Addyi REMS Program Patient-Provider Agreement Form.

☐

I will maintain the completed Addyi REMS Program Patient-Provider Agreement Form in the patient's records and provide the portion of the Patient-Provider Agreement designated for the patient receipt.

☐

I understand that the Addyi REMS Program may contact me via phone, mail, or email to survey me on the effectiveness of the REMS Program requirements.

☐

I will report any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals at 1-844-233-9415.

☐

Submit Attestations



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to the FDA.**

**Visit www.FDA.gov/medwatch
or call 1-800-FDA-1088.**



Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

Log In

Pharmacy Training, Enrollment, and Certification (3 Easy Steps)

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi™ (flibanserin) outweigh the increased risk of **hypotension and syncope** due to an interaction with alcohol.

Prescribers and Pharmacies must be certified in the Addyi REMS Program to prescribe and dispense Addyi. For pharmacies to successfully become certified they must complete the following 3 easy steps*:

1. **Read** the Addyi REMS Program Prescriber and Pharmacy Training and the Prescribing Information for Addyi. The Addyi REMS Program Prescriber and Pharmacy Training Program and Prescribing Information are available for download from this website (www.AddyiREMS.com) or they can be requested by calling the Addyi REMS Program Support Center (1-844-233-9415). You can also launch the Addyi REMS Program Prescriber and Pharmacy Training** (including the Knowledge Assessment) and enrollment process by clicking the appropriate button at the bottom of this webpage. (See **Option 1: Online** below for a description of the different pharmacies)
2. **Review** your knowledge by answering the questions contained within the Addyi REMS Program Knowledge Assessment.
3. **Enroll** in the Addyi REMS Program by completing the appropriate pharmacy enrollment process. Enrollment can be completed in 2 ways, online or fax.

* For online enrollment first sign-up by creating an account and providing all requested contact information.

Option 1: Online

Click on the appropriate button below to complete the Addyi REMS Program Prescriber and Pharmacy Training, knowledge assessment and enrollment online. Choose the button that best meets your needs.



Individual Location Outpatient Pharmacy Training Program, Certification and Enrollment

This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

CLICK HERE



Multiple Locations Outpatient Pharmacy Training Program, Certification and Enrollment

This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Clicking this button will take the authorized representative through the entire training, enrollment and certification process.

CLICK HERE

Materials for Prescribers

- ▶ Addyi REMS Program Prescriber and Pharmacy Training (Including a Knowledge Assessment)
- ▶ Addyi REMS Program Prescriber Enrollment Form
- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Prescribing Information
- ▶ Medication Guide

Materials for Pharmacies

- ▶ Addyi REMS Program Prescriber and Pharmacy Training (Including a Knowledge Assessment)
- ▶ Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form
- ▶ Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Prescribing Information
- ▶ Medication Guide

Materials for Patients

- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Medication Guide

Addyi REMS Program Support Center

⌚ Hours of Operation:
8:00 AM – 8:00 PM ET



outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

CLICK HERE

multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Clicking this button will take the authorized representative through the entire training, enrollment and certification process.

CLICK HERE



Inpatient Pharmacy Training Program, Certification and Enrollment

This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

CLICK HERE



Pharmacy Staff Training Program for all pharmacy staff at Addyi REMS Program Certified Pharmacies.

Clicking on this button will take pharmacy staff through the appropriate training should they wish to take the Addyi REMS Program training online. After completion, pharmacy staff will be able to print a Certificate of Completion which an authorized representative can use as documentation of the training requirements of the Addyi REMS Program.

CLICK HERE

Materials for Patients

- ▶ Addyi REMS Program Patient-Provider Agreement Form
- ▶ Medication Guide

Addyi REMS Program Support Center

🕒 **Hours of Operation:**
8:00 AM – 8:00 PM ET

✉ **Email:**
AddyiREMSsupport@AddyiREMS.com

📞 **Phone:** 1-844-233-9415

📠 **Fax:** 1-844-694-3373

Sprout Customer Service

📞 **Phone:** 1-844-746-5745

Option 2: Fax

Complete the appropriate enrollment form located on the right side of this page located under the heading Materials for Pharmacies and the Knowledge Assessment. Please fax all pages of the completed enrollment form and Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. You may also call the Addyi REMS Program Support Center (1-844-233-9415) to request the appropriate materials be sent to you.

** Note the training program is also available to pharmacy staff to meet the training requirements of the Addyi REMS Program.

addyi™
(flibanserin)

Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search



Individual Location Outpatient Pharmacy Training Program, Certification and Enrollment

This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the training, enrollment and certification process.

Click



Multiple Locations Outpatient Pharmacy Training Program, Certification and Enrollment

This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must

You have chosen *Individual Location Outpatient Pharmacy*



Are you sure this pharmacy type is the correct choice for your pharmacy? If so, please confirm below. If not, please close this window to select the correct pharmacy type.

Confirm

Inpatient Pharmacy Training Program, Certification and Enrollment

This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

Pharmacy Staff Training Program for all pharmacy staff at Addyi REMS Certified Pharmacies.

Clicking on this button will take pharmacy staff through the appropriate training should they wish to take the Addyi REMS training online. After completion, pharmacy staff will be able to print a Certificate of Completion which an authorized representative can use as

Addyi REMS Program Patient-Provider Agreement Form

Prescribing Information

Medication Guide

Materials for Patients

Addyi REMS Program Patient-Provider Agreement Form

Medication Guide

REMS Support Center

Hours of Operation:
8:00 AM – 8:00 PM ET

Email:
REMSupport@AddyiREMS.com

Phone: 1-844-233-9415

Fax: 1-844-694-3373

Sprout Customer Service

Phone: 1-844-746-5745

Option 2: Fax

Complete the appropriate enrollment form located on the right side of this page located under the heading Materials for Pharmacies and the Knowledge Assessment. Please fax all pages of the completed enrollment form and Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. You may also call the Addyi REMS Support Center (1-844-233-9415) to request the appropriate materials be sent to you.

addyiTM
(flibanserin)

Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Reference ID: 3808140 Search



Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

Log In

Addyi REMS Program Individual Location Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Complete All Fields Below

First Name

Last Name

Email

Phone Number

Fax Number

Your Profession

☐ R.Ph. ☐ PharmD ☐ Tech ☐ Other

Preferred Method of Contact

☐ Fax ☐ Email

NPI

NCPDP

DEA

Pharmacy Name

Pharmacy Store # (optional)

Address 1

Address 2

City

State

Zip Code

Submit to Proceed to Addyi REMS Program Prescriber and Pharmacy Training

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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

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Addyi REMS Program Support Center: 1-844-233-9415

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and Certification \(3 Easy Steps\)](#)

[Pharmacy Training, Enrollment,
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[Addyi Certified Pharmacy Network](#)

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Addyi REMS Program Prescriber and Pharmacy Training



Addyi™ REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Sprout Pharmaceuticals, Inc.
4208 Six Forks Rd, Suite 1010
Raleigh, NC 27609

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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

Log In

Addyi REMS Program Prescriber and Pharmacy Training

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

Take the Knowledge Assessment



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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

Log In

Addyi REMS Program Knowledge Assessment

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

1. Why is alcohol contraindicated with Addyi?

- ☐ Hepatotoxicity
- ☐ Teratogenicity
- ☐ Hypotension and syncope
- ☐ Hypersensitivity

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

- ☐ For prescribers to counsel patients at the office visit
- ☐ For patient charting
- ☐ For the patient to take home the important safety messages
- ☐ For pharmacy counseling
- ☐ All of the above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

- ☐ Never
- ☐ Only if the patient asks about alcohol use
- ☐ With the first prescription only
- ☐ With every prescription

4. What is the primary counseling message for the patient?

- ☐ Do not drink alcohol while taking Addyi until you know how alcohol affects you
- ☐ Limit your alcohol use while taking Addyi
- ☐ You must not drink alcohol while taking Addyi
- ☐ Do not drink alcohol at night when you take your daily Addyi

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**Visit www.FDA.gov/medwatch
or call 1-800-FDA-1088.**

Individual Location Outpatient Pharmacy Attestations (for Authorized Representative)

Please click to attest to each of the following statements:

Attest

1. I have read the Addyi REMS Program Prescriber and Pharmacy Training, the Addyi Medication Guide, and the Prescribing Information; and successfully completed the Addyi REMS Program Knowledge Assessment. ☐
2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol. ☐
3. My certified pharmacy must complete training of pharmacists and staff involved with the dispensing of Addyi using the Addyi REMS Program Prescriber and Pharmacy Training and must comply with the REMS requirements. This training will be documented and is subject to audit. ☐
4. I will ensure my certified pharmacy counsels patients to abstain from alcohol use with Addyi prior to dispensing. ☐
5. My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber. ☐
6. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088). ☐
7. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi. ☐
8. I will maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party. ☐
9. I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program. ☐
10. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program. ☐
11. I will oversee compliance with the Addyi REMS Program requirements. ☐
12. I understand that my certified outpatient pharmacy must verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi and will ensure verification through the following option (Click either Option A or B and indicate the NCPDP# as noted on the next page). ☐

[Click to Submit Attestations and Select Your Verification Option](#)



Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

Select the option that best matches your Pharmacy Management System (A or B)

OPTION A



Enter Your NCPDP#

My pharmacy utilizes a Pharmacy Management System (PMS) to transmit prescriptions electronically and will utilize this technology to verify prescriber certification.

I will ensure the following Pharmacy Management System requirements will be in place for my pharmacy.

1. The pharmacy management system configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements.
2. The pharmacy management system configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol with every dispensed prescription.
3. The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through the pharmacy management system and "pharmacy routing switch" for Addyi REMS verification of prescriber certification prior to dispensing every prescription.
4. I acknowledge that prior to Addyi REMS pharmacy certification, the Addyi REMS Program Support Center will contact me if an agreement is needed to permit the switch provider to use prescription data from this pharmacy to conduct the REMS.

OPTION B



Enter Your NCPDP#

My pharmacy does not utilize a Pharmacy Management System (PMS) to transmit prescriptions electronically and will verify prescriber certification through the Addyi REMS Program website or the Addyi REMS Program Support Center.

I will ensure my pharmacy staff will access the Addyi REMS Program website at www.AddyiREMS.com or call the Addyi REMS Program Support Center (1-844-233-9415) to confirm the authorizing prescriber is certified (as outlined in attestation 12) before dispensing each Addyi prescription. A complete authorization requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.

Complete Addyi REMS Program Prescriber and Pharmacy Training

ADDYI.com

**Visit www.FDA.gov/medwatch
or call 1-800-FDA-1088.**

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



Congratulations!

**You've completed the certification
process. Please see the directions below
for the remaining steps.**

Once your submission is successfully processed, you will receive a fax or e-mail with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. Upon successful verification of connectivity, you will be provided with the Terms & Conditions to become certified. Once this process is complete your pharmacy will receive a confirmation from the Addyi REMS Support Center and you will be considered certified and permitted to order, receive, and dispense Addyi.

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415.

[Return to Addyi REMS Home](#)



Individual Location Outpatient Pharmacy Training Program, Certification and Enrollment

This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

CLICK HERE



Multiple Locations Outpatient Pharmacy Training Program, Certification and Enrollment

This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Clicking this button

You have chosen *Multiple Locations Outpatient Pharmacy*

Are you sure this pharmacy type is the correct choice for your pharmacy? If so, please confirm below. If not, please close this window to select the correct pharmacy type.

Confirm



Inpatient Pharmacy Training Program, Certification and Enrollment

This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

Pharmacy Staff Training Program for all pharmacy staff at Addyi REMS Certified Pharmacies.

Clicking on this button will take pharmacy staff through the appropriate training should they wish to take the Addyi REMS training online. After completion, pharmacy staff will be able to print a Certificate of Completion which an authorized representative can use as

▶ Addyi REMS Program Patient-Provider Agreement Form

▶ Prescribing Information

▶ Medication Guide

Materials for Patients

▶ Addyi REMS Program Patient-Provider Agreement Form

▶ Medication Guide

REMS Support Center

Hours of Operation:

Monday – 8:00 PM ET

Email:

REMSupport@AddyiREMS.com

Phone: 1-844-233-9415

Fax: 1-844-694-3373

Sprout Customer Service

Phone: 1-844-746-5745

Option 2: Fax

Complete the appropriate enrollment form located on the right side of this page located under the heading Materials for Pharmacies and the Knowledge Assessment. Please fax all pages of the completed enrollment form and Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. You may also call the Addyi REMS Support Center (1-844-233-9415) to request the appropriate materials be sent to you.

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Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Reference ID: 3808140 **Search**



Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

[Prescriber Training, Enrollment,
and Certification \(3 Easy Steps\)](#)[Pharmacy Training, Enrollment,
and Certification \(3 Easy Steps\)](#)[Addyi Certified Pharmacy Network](#)[Log In](#)

Addyi REMS Program Multiple Locations Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Complete All Fields Below

First Name

Last Name

Email

Phone Number

Fax Number

Your Profession

☐ R.Ph. ☐ PharmD ☐ Tech ☐ Other

Preferred Method of Contact

☐ Fax ☐ Email

Pharmacy Name

Address 1

Address 2

City

State

Zip Code

[Submit to Proceed to Addyi REMS Program Prescriber and Pharmacy Training](#)

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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

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and Certification \(3 Easy Steps\)](#)

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Addyi REMS Program Prescriber and Pharmacy Training



Addyi™ REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Sprout Pharmaceuticals, Inc.
4208 Six Forks Rd, Suite 1010
Raleigh, NC 27609

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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

Log In

Addyi REMS Program Prescriber and Pharmacy Training

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

[Take the Knowledge Assessment](#)



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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

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Addyi REMS Program Support Center: 1-844-233-9415

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

Log In

Addyi REMS Program Knowledge Assessment

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

1. Why is alcohol contraindicated with Addyi?

- ☐ Hepatotoxicity
- ☐ Teratogenicity
- ☐ Hypotension and syncope
- ☐ Hypersensitivity

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

- ☐ For prescribers to counsel patients at the office visit
- ☐ For patient charting
- ☐ For the patient to take home the important safety messages
- ☐ For pharmacy counseling
- ☐ All of the above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

- ☐ Never
- ☐ Only if the patient asks about alcohol use
- ☐ With the first prescription only
- ☐ With every prescription

4. What is the primary counseling message for the patient?

- ☐ Do not drink alcohol while taking Addyi until you know how alcohol affects you
- ☐ Limit your alcohol use while taking Addyi
- ☐ You must not drink alcohol while taking Addyi
- ☐ Do not drink alcohol at night when you take your daily Addyi

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or call 1-800-FDA-1088.**

Multiple Locations Outpatient Pharmacy Attestations (for Authorized Representative)



Please click to attest to each of the following statements:

Attest

I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training, the Addyi Medication Guide, and the Prescribing Information and have successfully completed the Addyi REMS Program Knowledge Assessment.

☐

I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

☐

I will establish processes and procedures for all my certified outpatient pharmacy dispensing locations to ensure compliance with the requirements of the Addyi REMS Program before dispensing Addyi, including the following: (A) All certified outpatient pharmacy dispensing locations will complete training of pharmacists and staff involved with the dispensing of Addyi using the Addyi REMS Program Prescriber and Pharmacy Training and will comply with the REMS requirements. This training will be documented and is subject to audit. (B) All certified outpatient pharmacy dispensing locations will verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi. (C) All certified outpatient dispensing locations will counsel patients prior to dispensing the drug to abstain from alcohol consumption while undergoing treatment with Addyi. (D) All certified outpatient pharmacy dispensing locations will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.

☐

I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).

☐

I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.

☐

I will maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.

☐

I will comply with the audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.

☐

I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.

☐

I will oversee compliance with the Addyi REMS Program requirements.

☐

I will ensure the following Pharmacy Management System requirements will be in place for all certified outpatient pharmacy dispensing locations: (A) The Pharmacy Management System configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements. (B) The Pharmacy Management System configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol consumption with every dispensed prescription. (C) The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through our pharmacy management system and "pharmacy claims routing switch" for Addyi REMS verification of prescriber certification prior to dispensing every prescription.

☐

Proper authorization or provision of data rights to my switch provider are in place to meet Addyi REMS Program requirements.

☐

Complete Addyi REMS Program Prescriber and Pharmacy Training

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



Congratulations!

You've completed the certification process.

Upon receipt of all enrollment materials, you will receive a fax or email with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. After successful completion of the test transaction(s) you will receive a multiple pharmacy enrollment confirmation via fax and/or email from the Addyi REMS Program Support Center. Your multiple pharmacy entity will be considered certified and your retail chain dispensing locations will be eligible to complete their certification procedures.

[Return to Addyi REMS Home](#)



Individual Location Outpatient Pharmacy Training Program, Certification and Enrollment

This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.



Multiple Locations Outpatient Pharmacy Training Program, Certification and Enrollment

This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Clicking this button

▶ Addyi REMS Program Patient-Provider Agreement Form

▶ Prescribing Information

▶ Medication Guide

Materials for Patients

▶ Addyi REMS Program Patient-Provider Agreement Form

Guide

Support Center

Operation:

10 PM ET

support@AddyiREMS.com

1-844-233-9415

1-844-694-3373

Sprout Customer Service

Phone: 1-844-746-5745

Inpatient Program

This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

Clicking on this button will take pharmacy staff through the appropriate training should they wish to take the Addyi REMS training online. After completion, pharmacy staff will be able to print a Certificate of Completion which an authorized representative can use as

You have chosen *Inpatient Pharmacy*



Are you sure this pharmacy type is the correct choice for your pharmacy? If so, please confirm below. If not, please close this window to select the correct pharmacy type.

Confirm

Option 2: Fax

Complete the appropriate enrollment form located on the right side of this page located under the heading Materials for Pharmacies and the Knowledge Assessment. Please fax all pages of the completed enrollment form and Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. You may also call the Addyi REMS Support Center (1-844-233-9415) to request the appropriate materials be sent to you.

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(flibanserin)

Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Reference ID: 3808140 **Search**



Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

[Prescriber Training, Enrollment,
and Certification \(3 Easy Steps\)](#)[Pharmacy Training, Enrollment,
and Certification \(3 Easy Steps\)](#)[Addyi Certified Pharmacy Network](#)[Log In](#)

Addyi REMS Program Inpatient Pharmacy Information Intake Form (for Authorized Representative)

Complete All Fields Below

First Name

Last Name

Email

Phone Number

Fax Number

Your Profession

☐ R.Ph. ☐ PharmD ☐ Tech ☐ Other

Preferred Method of Contact

☐ Fax ☐ Email

NPI

NCPDP

DEA

Facility Name

Address 1

Address 2

City

State

Zip Code

[Submit to Proceed to the Addyi REMS Program Prescriber and Pharmacy Training](#)

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Reference ID: 3808140

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Addyi REMS Program Prescriber and Pharmacy Training



Addyi™ REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Sprout Pharmaceuticals, Inc.
4208 Six Forks Rd, Suite 1010
Raleigh, NC 27609

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Prescriber Training, Enrollment,
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Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

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Addyi REMS Program Prescriber and Pharmacy Training

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

[Take the Knowledge Assessment](#)



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Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

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Addyi REMS Program Knowledge Assessment

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

1. Why is alcohol contraindicated with Addyi?

- ☐ Hepatotoxicity
- ☐ Teratogenicity
- ☐ Hypotension and syncope
- ☐ Hypersensitivity

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

- ☐ For prescribers to counsel patients at the office visit
- ☐ For patient charting
- ☐ For the patient to take home the important safety messages
- ☐ For pharmacy counseling
- ☐ All of the above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

- ☐ Never
- ☐ Only if the patient asks about alcohol use
- ☐ With the first prescription only
- ☐ With every prescription

4. What is the primary counseling message for the patient?

- ☐ Do not drink alcohol while taking Addyi until you know how alcohol affects you
- ☐ Limit your alcohol use while taking Addyi
- ☐ You must not drink alcohol while taking Addyi
- ☐ Do not drink alcohol at night when you take your daily Addyi

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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

Inpatient Pharmacy Attestations (for Authorized Representative)

x

Please click to attest to each of the following statements:

Attest

I have read the Addyi REMS Program Prescriber and Pharmacy Training, the Addyi Medication Guide and the full Prescribing Information and have successfully completed the Addyi REMS Program Knowledge Assessment.

☐

I understand that there is an increased risk of syncope and hypotension associated with Addyi due to an interaction with alcohol.

☐

I will ensure that my inpatient pharmacy does not dispense Addyi for outpatient use.

☐

I understand that pharmacies within or associated with my healthcare facility that dispense drugs to outpatients must be separately certified as a certified outpatient pharmacy and comply with the Addyi REMS Program requirements to dispense Addyi to outpatients.

☐

I understand that a prescriber who wants to discharge a patient with an Addyi prescription, intended to be dispensed by an outpatient pharmacy, will be required to enroll in the Addyi REMS Program.

☐

My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.

☐

I will ensure all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).

☐

I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative.

☐

I will maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.

☐

I will comply with audits by to Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.

☐

I understand Addyi REMS Program personnel may contact pharmacists at certified inpatient hospital pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.

☐

I will oversee compliance with the Addyi REMS Program requirements.

☐

Submit Attestations

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



Congratulations!

You've completed the certification process.

Upon receipt the Addyi REMS Program Support Center will contact you to complete the certification process.

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415 or visit www.AddyiREMS.com.

[Return to Addyi REMS Home](#)



Individual Location Outpatient Pharmacy Training Program, Certification and Enrollment

This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.



Multiple Locations Outpatient Pharmacy Training Program, Certification and Enrollment

This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to

You have chosen *Pharmacy Staff Training*



This selection enables the healthcare professional to view the Addyi REMS Program Prescriber and Pharmacy Training and complete the Knowledge Assessment. If this was the selection you intended click to confirm. If not, please close this window to select the correct pharmacy type.

Confirm

Inpatient Program, Certification and Enrollment

This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

For an pharmacy staff at Addyi REMS Certified Pharmacies.

Clicking on this button will take pharmacy staff through the appropriate training should they wish to take the Addyi REMS training online. After completion, pharmacy staff will be able to print a Certificate of Completion which an authorized representative can use as

▶ Addyi REMS Program Patient-Provider Agreement Form

▶ Prescribing Information

▶ Medication Guide

Materials for Patients

▶ Addyi REMS Program Patient-Provider Agreement Form

▶ Medication Guide

Addyi REMS Support Center

🕒 **Hours of Operation:**
8:00 AM – 8:00 PM ET

✉ **Email:**
AddyiREMSsupport@AddyiREMS.com

📞 **Phone:** 1-844-233-9415

📠 **Fax:** 1-844-694-3373

Sprout Customer Service

📞 **Phone:** 1-844-746-5745

Option 2: Fax

Complete the appropriate enrollment form located on the right side of this page located under the heading Materials for Pharmacies and the Knowledge Assessment. Please fax all pages of the completed enrollment form and Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. You may also call the Addyi REMS Support Center (1-844-233-9415) to request the appropriate materials be sent to you.

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(flibanserin)

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Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Reference ID: 3808140 **Search**



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This website is intended for US Healthcare Professionals

Addyi REMS Program Support Center: 1-844-233-9415

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[Addyi Certified Pharmacy Network](#)

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Addyi REMS Program Prescriber and Pharmacy Training



Addyi™ REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

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Addyi REMS Program Prescriber and Pharmacy Training

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

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Addyi REMS Program Knowledge Assessment

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

1. Why is alcohol contraindicated with Addyi?

- ☐ Hepatotoxicity
- ☐ Teratogenicity
- ☐ Hypotension and syncope
- ☐ Hypersensitivity

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

- ☐ For prescribers to counsel patients at the office visit
- ☐ For patient charting
- ☐ For the patient to take home the important safety messages
- ☐ For pharmacy counseling
- ☐ All of the above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

- ☐ Never
- ☐ Only if the patient asks about alcohol use
- ☐ With the first prescription only
- ☐ With every prescription

4. What is the primary counseling message for the patient?

- ☐ Do not drink alcohol while taking Addyi until you know how alcohol affects you
- ☐ Limit your alcohol use while taking Addyi
- ☐ You must not drink alcohol while taking Addyi
- ☐ Do not drink alcohol at night when you take your daily Addyi

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Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



{Pharmacy Staff Name}

{Date of Completion}

Congratulations!

**You've completed the Addyi REMS Program
Prescriber and Pharmacy Training and
Knowledge Assessment.**

 [Click here to print.](#)

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Risk Evaluation and Mitigation Strategy (REMS) FDA REQUIRED REMS SAFETY INFORMATION

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Addyi REMS Program Support Center: 1-844-233-9415

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Addyi Certified Networks



Addyi Certified Pharmacy Network

Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search

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Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

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and Certification (3 Easy Steps)


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Addyi REMS Program Support Center

 **Hours of Operation:** 8:00 AM – 8:00 PM ET

 **Phone:** 1-844-233-9415

 **Fax:** 1-844-694-3373

 **Email:** AddyiREMSsupport@AddyiREMS.com

For questions or requests pertaining to the Addyi REMS Program please contact the Addyi REMS Support Center.

Sprout Pharmaceuticals, Inc. Customer Service

 **Phone:** 1-844-746-5745

 **Email:** AddyiREMS@sproutpharma.com

Mailing Address:

4208 Six Forks Road
Suite 1010
Raleigh, NC 27609

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APPENDIX E: ADDYI REMS PROGRAM PATIENT-PROVIDER AGREEMENT FORM

Addyi™ REMS Program

Patient-Provider Agreement Form

Healthcare Provider:

- Alcohol use is contraindicated in women taking Addyi™ (flibanserin)
- Addyi and alcohol interact and increase the risk of severe hypotension and syncope.
- I agree to:
 - Use this Patient-Provider Agreement Form to counsel my patients about these risks and the importance of abstaining from alcohol.
 - Sign this form along with my patient and place a copy in her chart.
 - **Tear off** the bottom portion and provide it to my patient to take home for her reference.

Prescriber Signature _____ Date _____

Pharmacist: This form may be used as an optional tool for counseling patients. No charting or signatures are required.

Patient:

I understand that I must not drink alcohol while taking Addyi. Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.
- I understand the instructions that my healthcare provider has given to me.

Patient Signature _____ Date _____

tear here

addyi™
(flibanserin)

Addyi™ Patient Information

I understand that I must not drink alcohol while taking Addyi (flibanserin). Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

For more information about Addyi please visit www.AddyiREMS.com

APPENDIX F: ADDYI REMS PROGRAM MULTIPLE LOCATION PHARMACY
ENROLLMENT FORM

Addyi™ REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for Addyi™ (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. For outpatient use, Addyi is only available from certified outpatient prescribers and certified outpatient pharmacies through the Addyi REMS Program. For inpatient use, Addyi is only available from certified inpatient pharmacies through the Addyi REMS Program.

Only certified pharmacies can dispense Addyi. This helps ensure that patients starting or continuing treatment with Addyi are counseled appropriately about the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol.

As the **Authorized Pharmacy Representative** for your multiple locations outpatient pharmacy, you must do the following:

- Ensure all your outpatient pharmacy dispensing locations utilize a pharmacy management system to submit all Addyi prescriptions in accordance with the Addyi REMS program requirements.
- Review the *Addyi REMS Program Prescriber and Pharmacy Training Program*, *Addyi Medication Guide*, and *Prescribing Information* for Addyi.
- Successfully complete and submit the *Addyi REMS Program Knowledge Assessment* and this *Addyi REMS Multiple Locations Outpatient Pharmacy Enrollment Form*. This may be done online at www.AddyiREMS.com or by completing both in hard copy and submitting via fax or email to the Addyi REMS Program Support Center.
- Implement the necessary staff training and processes at both a headquarters level and at each dispensing location to comply with the Addyi REMS Program requirements.

Authorized Multiple Locations Outpatient Pharmacy Representative Acknowledgement

I understand that Addyi can only be dispensed by certified pharmacies and, to become certified, all my outpatient pharmacy dispensing locations must comply with the Addyi REMS Program requirements. As an Authorized Pharmacy Representative, I acknowledge that:

1. I have reviewed the *Addyi REMS Program Prescriber and Pharmacy Training Program*, the *Addyi Medication Guide*, and the *Prescribing Information* and have successfully completed the *Addyi REMS Program Knowledge Assessment*.
2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
3. I will establish processes and procedures for all my certified outpatient pharmacy dispensing locations to ensure compliance with the requirements of the Addyi REMS Program before dispensing Addyi, including the following:
 - a. All certified outpatient pharmacy dispensing locations will complete training of pharmacists and staff involved with the dispensing of Addyi using the *Addyi REMS Program Prescriber and Pharmacy Training Program* and will comply with the REMS requirements. This training will be documented and is subject to audit.
 - b. All certified outpatient pharmacy dispensing locations will verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi.

Addyi[™] REMS Program
Multiple Locations Outpatient Pharmacy Enrollment Form

- c. All certified outpatient dispensing locations will counsel patients prior to dispensing the drug to abstain from alcohol consumption while undergoing treatment with Addyi.
 - d. All certified outpatient pharmacy dispensing locations will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.
- 4. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope *where an interaction with alcohol cannot be ruled out* to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).
 - 5. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.
 - 6. I will maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide such documentation upon request to Sprout Pharmaceuticals, FDA, or a third party.
 - 7. I will comply with the audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
 - 8. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.
 - 9. I will oversee compliance with the Addyi REMS Program requirements.
 - 10. I will ensure the following Pharmacy Management System requirements will be in place for all certified outpatient pharmacy dispensing locations:
 - a. The Pharmacy Management System configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements.
 - b. The Pharmacy Management System configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol consumption with every dispensed prescription.
 - c. The Pharmacy Management System configuration must process all Addyi prescriptions, regardless of the method of payment, through our pharmacy management system and “pharmacy claims routing switch” for Addyi REMS verification of prescriber certification prior to dispensing every prescription.
 - 11. Proper authorization or provision of data rights to my switch provider are in place to meet Addyi REMS Program requirements.

Please complete all the information requested on the next page.



Addyi™ REMS Program
Multiple Locations Outpatient Pharmacy Enrollment Form

Authorized Multiple Locations Outpatient Pharmacy Representative to complete (all fields required):

First Name _____ Last Name _____

Phone Number _____ Fax _____

Email _____

Multiple Locations Pharmacy Name _____

Chain ID # _____

Address _____ City _____

State _____ Zip Code _____

Signature _____ Date _____

Authorized Multiple Locations Outpatient Pharmacy Representative

Preferred Method of Communication (please select one): ☐ Fax ☐ Email

Please fax all pages of this form and the completed *Addyi REMS Program Knowledge Assessment* to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com.

Once this form is successfully processed, you will receive a fax or e-mail with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS program.

After successful completion of the test transaction(s) you will receive a multiple pharmacy enrollment confirmation via fax and/or email from the Addyi REMS Program Support Center. Your multiple pharmacy entity will be considered certified and your retail chain dispensing locations will be eligible to complete their certification procedures.

The *Addyi REMS Program Prescriber and Pharmacy Training Program* for your pharmacy dispensing locations will be made available through the Addyi REMS Support Center. Once the training program and knowledge assessment are completed at a pharmacy dispensing location within your organization, it is your responsibility to capture the pharmacy dispensing location information noted below and provide this information to the Addyi REMS Program Support Center. Once the Addyi REMS Program Support Center receives, processes, and confirms the required pharmacy dispensing location information from you, this pharmacy dispensing location will be considered certified and permitted to order, receive, and dispense Addyi.

The following required pharmacy dispensing location fields must be provided to the Authorized Multiple Pharmacy Representative for each trained pharmacy dispensing location: Responsible Pharmacist first and last name, dispensing pharmacy address with zip code, phone and fax numbers, pharmacy NCPDP ID, NPI and DEA numbers; and pharmacy store # (if applicable).

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415.

APPENDIX G: ADDYI REMS PROGRAM INDIVIDUAL LOCATION PHARMACY
ENROLLMENT FORM

Addyi™ REMS Program Individual Location Outpatient Pharmacy Enrollment Form

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for Addyi™ (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. For outpatient use, Addyi is only available from certified outpatient prescribers and certified outpatient pharmacies through the Addyi REMS Program.

Only certified pharmacies can dispense Addyi. This helps ensure that patients starting or continuing treatment with Addyi are counseled appropriately about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

As the **Authorized Pharmacy Representative** for this outpatient pharmacy, you must do the following:

- Review the *Addyi REMS Program Prescriber and Pharmacy Training Program*, *Addyi Medication Guide*, and *Prescribing Information* for Addyi.
- Successfully complete and submit the *Addyi REMS Program Knowledge Assessment* and the *Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form*. This may be done online at www.AddyiREMS.com or by completing both in hard copy and submitting via fax or email to the Addyi REMS Support Center.
- Implement the necessary staff training and processes at your outpatient pharmacy to comply with the Addyi REMS Program requirements.

Authorized Individual Location Outpatient Pharmacy Representative Acknowledgement

I understand that Addyi can only be dispensed by certified pharmacies and, to become certified, my outpatient pharmacy must comply with the Addyi REMS Program requirements. As an Authorized Pharmacy Representative, I acknowledge that:

1. I have reviewed the *Addyi REMS Program Prescriber and Pharmacy Training Program*, the Addyi Medication Guide, and the Prescribing Information; and successfully completed the *Addyi REMS Program Knowledge Assessment*.
2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
3. My certified pharmacy must complete training of pharmacists and staff involved with the dispensing of Addyi using the *Addyi REMS Program Prescriber and Pharmacy Training Program* and must comply with the REMS requirements. This training will be documented and is subject to audit.
4. I will ensure my certified pharmacy counsels patients to abstain from alcohol use with Addyi prior to dispensing.
5. My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.
6. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).

7. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.
8. I will maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide such documentation upon request to Sprout Pharmaceuticals, FDA, or a third party.
9. I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
10. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.
11. I will oversee compliance with the Addyi REMS Program requirements.
12. I understand that my certified outpatient pharmacy must verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi and will ensure verification through the following option **(Place a check next to either Option A or B and indicate the NCPDP# as noted on the next page)**.

Please complete all the information requested on the following pages.

Addyi™ REMS Program Individual Location Outpatient Pharmacy Enrollment Form

Please indicate your Pharmacy NCPDP# next to your preferred Option A or B based on how you will process dispensing transactions for the Addyi REMS Program.

<input type="checkbox"/> Option A NCPDP# _____	<input type="checkbox"/> Option B NCPDP# _____
My pharmacy utilizes a Pharmacy Management System (PMS) to transmit prescriptions electronically and will utilize this technology to verify prescriber certification.	My pharmacy <u>does not</u> utilize a Pharmacy Management System (PMS) to transmit prescriptions electronically and will verify prescriber certification through the Addyi REMS Program website or the Addyi REMS Program Support Center.
<p>I will ensure the following Pharmacy Management System requirements will be in place for my pharmacy.</p> <ul style="list-style-type: none"> a. The pharmacy management system configuration and/or updates will be in place and verified with the Addyi REMS Pharmacy Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements. b. The pharmacy management system configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol with every dispensed prescription. c. The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through the pharmacy management system and “pharmacy routing switch” for Addyi REMS verification of prescriber certification prior to dispensing every prescription. d. I acknowledge that prior to Addyi REMS pharmacy certification, the Addyi REMS Support Center will contact me if an agreement is needed to permit the switch provider to use prescription data from this pharmacy to conduct the REMS. 	<p>I will ensure my pharmacy staff will access the Addyi REMS Program website at www.AddyiREMS.com or call the Addyi REMS Program Support Center (1-844-233-9415) to confirm the authorizing prescriber is certified (as outlined in attestation 12) before dispensing each Addyi prescription. A complete authorization requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber’s NPI or DEA.</p>

Please proceed to next page and provide required information.



Addyi™ REMS Program
Individual Location Outpatient Pharmacy Enrollment Form

Authorized Individual Location Outpatient Pharmacy Representative to complete (all fields required):

First Name _____ Last Name _____
Phone Number _____ Fax _____
Email _____
Address _____ City _____
State _____ Zip Code _____
Pharmacy Name _____
Pharmacy NCPDP ID _____ DEA Number _____
Pharmacy NPI _____ Pharmacy Store # (optional) _____
Signature _____ Date _____
Authorized Individual Location Outpatient Pharmacy Representative

Preferred Method of Communication (please select one): ☐ Fax ☐ Email

Please fax all pages of this form and the completed *Addyi REMS Program Knowledge Assessment* to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail both documents to AddyiREMSEnroll@AddyiREMS.com.

Once this form is successfully processed and the knowledge assessment has been successfully completed, you will receive a fax or e-mail with further information.

If you selected Option A above: You will receive instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. Upon successful verification of connectivity, you will be provided with the Terms & Conditions to become certified. Once this process is complete your pharmacy will receive a confirmation from the Addyi REMS Program Support Center and you will be considered certified and permitted to order, receive, and dispense Addyi.

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415.

APPENDIX H: ADDYI REMS PROGRAM INPATIENT PHARMACY ENROLLMENT
FORM

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for Addyi™ (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. For inpatient use, Addyi is only available from certified inpatient pharmacies through the Addyi REMS Program. For outpatient use, Addyi is only available from certified outpatient prescribers and certified outpatient pharmacies through the Addyi REMS Program.

Only certified pharmacies can dispense Addyi. This helps ensure that patients starting or continuing treatment with Addyi are counselled appropriately about the risks of hypotension and syncope associated with flibanserin due to an interaction with alcohol.

As the **Authorized Pharmacy Representative** for your facility's inpatient pharmacy, you must do the following:

- Review the *Addyi REMS Program Prescriber and Pharmacy Training Program*, *Addyi Medication Guide*, and *Prescribing Information for Addyi*.
- Successfully complete and submit the *Addyi REMS Program Knowledge Assessment* and this *Addyi REMS Program Inpatient Pharmacy Enrollment Form*. This may be done online at www.AddyiREMS.com or by completing both in hard copy and submitting via fax or email to the Addyi REMS Program Support Center.
- Implement the necessary staff training and processes in the facility's inpatient pharmacy to comply with the Addyi REMS Program requirements.

Authorized Inpatient Pharmacy Representative Acknowledgement

I understand that Addyi can only be dispensed by certified pharmacies and, to become certified, all my inpatient pharmacy must comply with the Addyi REMS Program requirements. As an Authorized Pharmacy Representative, I acknowledge that:

1. I have read the *Addyi REMS Program Prescriber and Pharmacy Training Program*, the *Addyi Medication Guide* and the full *Prescribing Information* and have successfully completed the *Addyi REMS Knowledge Assessment*.
2. I understand that there is an increased risk of syncope and hypotension associated with Addyi due to an interaction with alcohol.
3. I will ensure that my inpatient pharmacy does not dispense Addyi for outpatient use.
4. I understand that pharmacies within or associated with my healthcare facility that dispense drugs to outpatients must be separately certified as a certified outpatient pharmacy and comply with the Addyi REMS Program requirements to dispense Addyi to outpatients.
5. I understand that a prescriber who wants to discharge a patient with an Addyi prescription, intended to be dispensed by an outpatient pharmacy, will be required to enroll in the Addyi REMS Program.
6. My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.

7. I will ensure all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).
8. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative.
9. I will maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.
10. I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
11. I understand Addyi REMS Program personnel may contact pharmacists at certified inpatient hospital pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.
12. I will oversee compliance with the Addyi REMS Program requirements.

Authorized Inpatient Pharmacy Representative

Name* (please print):_____ **Date:**_____

NPI #*:_____

Complete all information requested on the following page.

Authorized Inpatient Pharmacy Representative

Signature* _____ Date _____
 First Name* _____ Last Name* _____ Title _____
 Phone Number* _____ Email* _____

***Required Fields**

Inpatient Pharmacy Information

Pharmacy Name* _____ NPI Number* _____
 Address* _____ Pharmacy License Number* _____
 City* _____ DEA Number* _____
 State* _____ ZIP* _____ Phone Number* _____
 Fax Number* _____

***Required Fields**

Preferred Method of Communication (please select one): ☐ Fax ☐ Email

Please fax all pages of this form and the completed Addyi REMS Program Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com.

Once processed, the Addyi REMS Program Support Center will contact you to complete the certification process.

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415 or visit www.AddyiREMS.com.