



Addyi[®] (flibanserin) 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.,
a wholly owned subsidiary of Valeant
Pharmaceuticals International, Inc.
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

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.



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](http://www.AddyiREMS.com).
- Further information is also available at www. AddyiREMS.com.

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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 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® 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® 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® 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

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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.
- Pharmacists must counsel patients about the need to avoid alcohol with every prescription.
- The **Addyi REMS Patient-Provider Agreement Form** is an important and required tool for healthcare providers to use with patients.

Addyi® REMS Program Patient-Provider Agreement

- The **AddyiREMS 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.**

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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

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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.

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? | <ul style="list-style-type: none"> a) Hepatotoxicity b) Teratogenicity | <ul style="list-style-type: none"> c) Hypotension and syncope d) Hypersensitivity |
| What is the purpose of the Addyi REMS Patient-Provider Agreement Form? | <ul style="list-style-type: none"> a) For prescribers to counsel patients at the office visit. b) For patient charting | <ul style="list-style-type: none"> 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? | <ul style="list-style-type: none"> a) Never b) Only if the patient asks about alcohol use | <ul style="list-style-type: none"> c) With the first prescription only d) With every prescription |
| What is the primary counseling message for the patient? | <ul style="list-style-type: none"> a) Do not drink alcohol while taking Addyi until you know how alcohol affects you. b) Limit your alcohol use while taking Addyi | <ul style="list-style-type: none"> 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#



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.

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