# PrADDYI® (flibanserin) Prescribing Checklist

Prior to prescribing ADDYI (flibanserin) the healthcare professional should consider using the Prescribing Checklist as a tool to confirm the patient's eligibility for treatment. If the patient is found to be eligible, an informed consent is to be obtained from the patient in accordance with provincial/territorial legislation and any standards/guidelines.

Pr addyi® (flibanserin) 100mg tablets

## About ADDYI

ADDYI is indicated for the treatment of premenopausal and naturally postmenopausal women ≤ 60 years of age with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire for a minimum of 6 months, which occurs 75-100% of the time, 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.

## ADDYI should not be prescribed to any patients with a NO response for questions 1-5

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|---|---|---|
| 1. In the past, was the patient's level of sexual desire or interest good and satisfying to them? | ◯ Yes | ◯ No |
| 2. Has there been a decrease in the patient's level of sexual desire or interest? | ◯ Yes | ◯ No |
| 3. Has sexual desire been decreased for over 6 months, 75-100% of the time? | ◯ Yes | ◯ No |
| 4. Is the patient bothered by their decreased level of sexual desire or interest? | ◯ Yes | ◯ No |
| 5. Would the patient like their level of sexual desire or interest to increase? | ◯ Yes | ◯ No |

## Clinical judgment should be used if prescribing ADDYI to patients with a YES response to any of the questions below, as a primary diagnosis other than HSDD may be present.

1. Are there any factors that may be contributing to their current decrease in sexual desire or interest?

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|---|---|---|
| A. An operation, depression, injuries, or other medical condition | ◯ Yes | ◯ No |
| B. Medications (ex. SSRIs), drugs, or level of alcohol they are currently taking | ◯ Yes | ◯ No |
| C. Recent childbirth, menopausal symptoms | ◯ Yes | ◯ No |
| D. Other sexual issues they may be having (pain, decreased arousal or orgasm) | ◯ Yes | ◯ No |
| E. Their partner's sexual problems | ◯ Yes | ◯ No |
| F. Dissatisfaction with their relationship or partner | ◯ Yes | ◯ No |
| G. Stress or fatigue | ◯ Yes | ◯ No |

## Contraindications for prescribing ADDYI:
## ADDYI should not be prescribed to any patients with a YES response to the questions below.

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|---|---|---|
| 1. Does the patient have hepatic impairment? | ◯ Yes | ◯ No |
| 2. Is patient pregnant or breastfeeding? | ◯ Yes | ◯ No |
| 3. Is patient currently using alcohol and has a resting systolic blood pressure <110 mmHg or diastolic blood pressure <60 mmHg? | ◯ Yes | ◯ No |
| 4. Is patient taking any moderate or strong CYP3A4 inhibitors? Some examples of moderate or strong CYP3A4 inhibitors include: ritonavir, flucanozole, ciprofloxacin, erythromycin, boceprevir, nefazodone and grapefruit juice.<br>Please consult the ADDYI Product Monograph for additional guidance. | ◯ Yes | ◯ No |
| 5. Does patient have hypersensitivity to flibanserin or other components of ADDYI? | ◯ Yes | ◯ No |
| 6. Does patient take P-glycoprotein (P-gp) substrates (digoxin)? | ◯ Yes | ◯ No |

## Patient counseling for safe use of ADDYI:
## Patients should be counseled on how to take ADDYI to promote safe use of the medication.

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|---|---|
| 1. ADDYI is dosed at bedtime because administration during waking hours increases the risks of hypotension, syncope, and CNS depression (such as somnolence and sedation). | ◯ Completed |
| 2. The importance of limiting their alcohol intake in combination with ADDYI, as the combination of ADDYI and alcohol may increase the risk of severe low blood pressure. | ◯ Completed |
| 3. The patient should be discouraged from driving, operating machinery or engaging in activities that require clear thinking until 6 hours after taking ADDYI and until they know how it may affect them. | ◯ Completed |
| 4. If patient misses a dose, they should be instructed to skip that dose and take their next dose at bedtime of the following day. Increased doses are not associated with greater effect and can increase the risks of side effects. | ◯ Completed |
| 5. ADDYI must be used with caution in patients with any pre-existing cardiovascular conditions. Side effects from ADDYI use have included tachycardia, palpitations, hypotension and syncope. | ◯ Completed |
| 6. Patient should be cautioned that not all women benefit from treatment with ADDYI. Treatment should be discontinued after 8 weeks if there has been no improvement. | ◯ Completed |
| 7. Patient gives consent to treatment with ADDYI. | ◯ Completed |
| 8. Patient has been given a copy of the “Patient Handout”. | ◯ Completed |

**For additional information please consult the ADDYI Product Monograph**

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REVIEWED BY PAAB