

Once-daily only at bedtime, 100mg qhs





CODING • ICD-10-CM HSDD is F52.0 • ICD-11 HSDD is HA00.2 FOR HSDD** DSDS/FSFI screeners, if administered, are CPT 96127

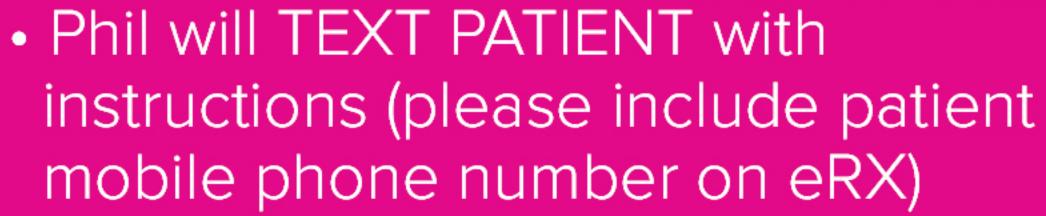
*Coding is at the discretion of the HCP and does not guarantee reimbursement

PHARMACY (4phil)

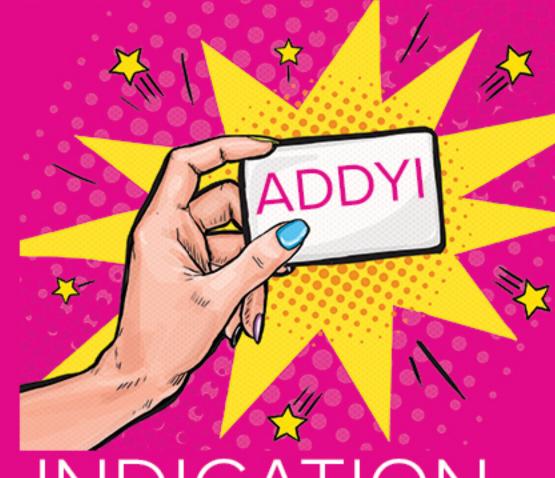
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RETAIL PICK-UP

COPAY CARD NEEDED

 A copay card for the pharmacy must be downloaded at: addyi.com/savings

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. Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner. Addyi is not indicated for the treatment of HSDD in postmenopausal women, men or to enhance sexual performance.

SELECTED IMPORTANT SAFETY INFORMATION

WARNING: HYPOTENSION AND SYNCOPE IN CERTAIN SETTINGS

- See full prescribing information for complete boxed warning.

 Use of ADDYI and alcohol together close in time increases the risk of severe hypotension and syncope. Counsel patients to wait at least two hours after consuming one or two standard alcoholic drinks before taking ADDYI at bedtime or to skip their ADDYI dose if they have consumed three or more alcoholic drinks that evening.
- Severe hypotension and syncope can occur when ADDYI is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, ADDYI use in these settings is contraindicated.

See additional Important Safety Information, including Boxed Warning regarding hypotension and syncope in certain settings, on back and Full Prescribing Information and Medication Guide at addyi.com/pi.

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Contraindications

Moderate or strong cytochrome P450 3A4 (CYP3A4) inhibitors

Hepatic impairment

Warnings and Precautions

 Hypotension and Syncope Due to an Interaction with Alcohol: Taking ADDYI within two hours after consuming alcohol
increases the risk of severe hypotension and syncope. To reduce this risk, counsel patients to wait at least two hours after
drinking one or two standard alcoholic drinks before taking ADDYI at bedtime. Patients who drink three or more standard
alcoholic drinks should skip their ADDYI dose that evening. After taking ADDYI at bedtime, advise patients to not use alcohol until the following day.

 Hypotension and Syncope with CYP3A4 Inhibitors: Moderate or strong CYP3A4 inhibitors significantly increase ADDYI concentrations, which can lead to hypotension and syncope. Concomitant use of ADDYI with a moderate or strong CYP3A4 inhibitor is contraindicated. Concomitant use of multiple weak CYP3A4 inhibitors that may include herbal supplements (e.g., ginkgo, resveratrol) or non-prescription drugs (ė.g., cimetidine) could also lead to ćlinically relevant increases in

flibanserin concentrations that may increase the risk of hypotension and syncope.

 Central Nervous System (CNS) Dépression (e.g., Somnolènce, Sedation): Can occur with ADDYI alone and is exacerbated by other CNS depressants including alcohol, and in settings where flibanserin concentrations are increased such as CYP3A4 inhibitors. The risk of CNS depression is also increased if ADDYI is taken during waking hours. Patients should avoid activities requiring full alertness (e.g., operating machinery or driving) until at least six hours after each dose and until they know how ADDYI affects them.

 Hypotension and Syncope with ADDYI Alone: The use of ADDYI - without other concomitant medications known to cause hypotension or syncope - can cause hypotension and syncope. The risk of hypotension and syncope is increased if ADDYI is taken during waking hours or if higher than the recommend dose is taken. Consider the benefits of ADDYI and the risks of hypotension and syncope in patients with pre-existing conditions that predispose to hypotension. Patients with pre-syncope should immediately lie supine and promptly seek medical help if symptoms do not resolve. Prompt medical attention should also be obtained for patients who experience syncope.

• Syncope and Hypotension in Patients with Hepatic Impairment: Any degree of hepatic impairment significantly increases flibánserin concentrations, which can lead to hypotensión and syncope. ADDYI is contraindicated in patients with hepatic

impairment.

Drug Interactions

• Alcohol: coadministration of ADDYI with alcohol increased the risk of hypotension, syncope, and CNS depression compared to the use of ADDYI alone or alcohol alone. Patients should wait at least two hours after consuming one or two standard alcoholic drinks before taking ADDYI at bedtime or to skip their ADDYI dose if they have consumed three or more alcoholic drinks that evening.

• CNS Depressants: (i.e., diphenhydramine, opioids, hypnotics, benzodiazepines, etc.) Concomitant use with ADDYI may increase the risk of CNS depression compared to use of ADDYI alone.

 Moderate or Strong CYP3A4 Inhibitors: ADDYI is contraindicated in women taking moderate (e.g., fluconazole, etc.) or strong (e.g., ketoconazole, etc.) CYP3A4 inhibitors

• Oral Contraceptives and Other Weak CYP3A4 Inhibitors: In combination with ADDYI may increase the risk of adverse reactions

Strong CYP2C19 Inhibitors: (i.e., proton pump inhibitors, SSRI's, benzodiazepines, antifungals, etc.) Increase flibanserin exposure which may increase risk of hypotension, syncope, and CNS depression
 CYP3A4 Inducers: (i.e., carbamazepine, phenobarbital, etc.) Concomitant use substantially decreases flibanserin exposure compared to the use of ADDYI along and is not recommended.

 Digoxin or other P-glycoprotein (P-gp) substrates: Increases digoxin concentration, which may lead to digoxin toxicity. Increase monitoring of drugs transported by P-qp that have a narrow therapeutic index.

Most Common Adverse Reactions

 Most common adverse reactions (ADDYI incidence ≥2% and higher than placebo) are dizziness, somnolence, nausea, fatique, insomnia, and dry mouth.

See Indication and additional Important Safety Information, including Boxed Warning regarding hypotension and syncope in certain settings, on reverse and Full Prescribing Information and Medication Guide at addyi.com/pi.