Generic Name:
Flibanserin
Trade Name:
Addyi
Company:
Sprout Pharmaceuticals
Notes:

On April 11, 2019, FDA announced that changes must be made to the labeling for flibanserin to clarify that there is still a concern about consuming alcohol close in time to taking the drug, but that alcohol does not have to be avoided completely.

Specifically, the boxed warning, contraindication, warnings and precautions, and adverse reactions sections of labeling are being updated to reflect that women should discontinue drinking alcohol at least 2 hours before taking flibanserin at bedtime or to skip the flibanserin dose that evening. Women should not consume alcohol at least until the morning after taking flibanserin at bedtime.

FDA is ordering this safety labeling change because the agency was not able to reach an agreement with the manufacturer, Sprout Pharmaceuticals. The company was continuing to request removal of the boxed warning and contraindication about alcohol completely from the product labeling. FDA determined, based on a careful review of available data, that to protect public health, removing this important safety information was not acceptable.

The agency's decision to order modifications to the warnings about flibanserin and alcohol, instead of removing the boxed warning and contraindication completely, was based on two sets of postmarket research studies.

Flibanserin is a serotonin 1A receptor agonist and a serotonin 2A receptor antagonist, but the mechanism by which the drug improves sexual desire and related distress is not known. The drug is taken once daily at bedtime to help decrease the risk of adverse events from possible hypotension, syncope, and CNS depression (such as sleepiness and sedation). Patients should stop treatment after 8 weeks if they do not have an improvement in sexual desire and associated distress.

The drug's most common adverse reactions are dizziness, sleepiness, nausea, fatigue, insomnia, and dry mouth.

Medication Monitor Categories:
Alerts and Recalls