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Addyi- Change the Women's Sexual Satisfying Event.

Shashank Tiwari*.

Senior Scientist, Department of Pharmacy, Integrated Biotechnological Research Institute, Lucknow, INDIA.

ABSTRACT

Addyi is the First United State Food and Drug Administration Approved women's drug for the treatment of Hypoactive Sexual Desire Disorder. FDA finally given green light the drug in August 2015 after two rejection. Addyi is non-hormonal pills. The generic name of Addyi is Flibanserin. But Addyi is the different formViagra. The Addyi is prepared in oral dosage form table with contain 100mg of drug. It boosts the women's sexual satisfaction level but the FDA clearly mentioned, if no improvement in women's sexual desire within 8 month, they should discontinue.

Keywords: Addyi, Desire, Female, FDA, Sex

Corresponding author

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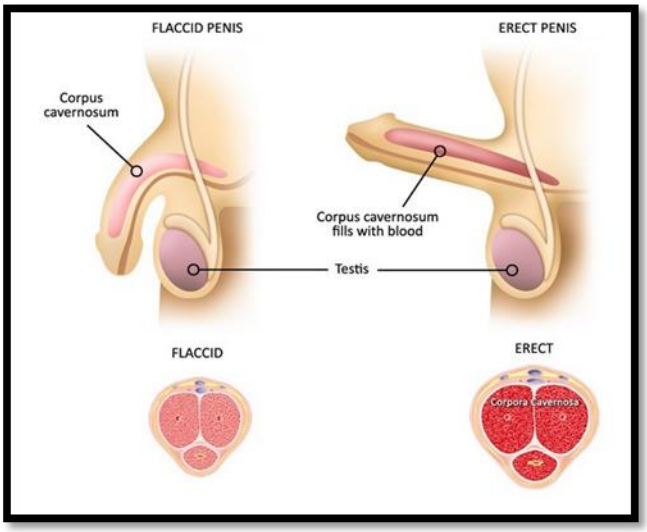
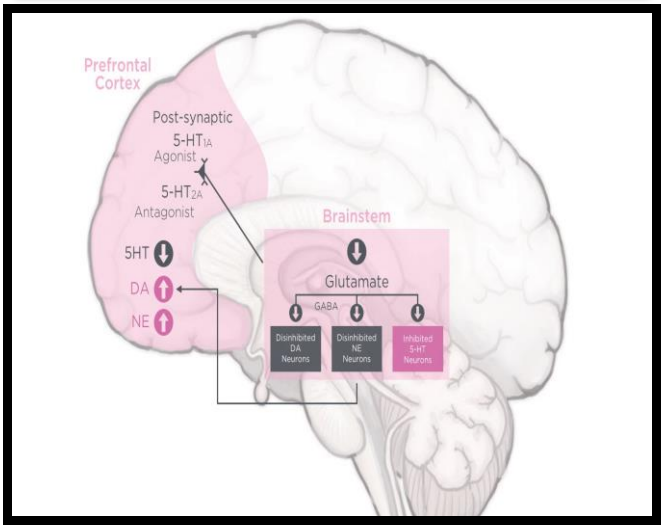
INTRODUCTION

Addyiis a brand name manufactured by Sprout Pharmaceuticals a division of Valeant Pharmaceuticals North America.The generic name of Addyi is Flibanserin. The Addyi is very controversial drug designed since last few years but United State Food and Drug Administration finally officially approved drug for the treatment of hypoactive sexual desire disorder. The Hypoactive Sexual Desire Disorder (HSDD) is the very common female sexual dysfunction.

Addyiacts in brain to increase the women's sexual desire and average increased their number of satisfying sexual events by 3 to 4 weeks. The Flibanserin is different for the Viagra, the Viagra rise the blood flow to the penis when a man is Kindled but they do not increase male libido. In the case of flibanserin, they focusing on the hormones and brain chemicals that affect women libodo.it is clearly blood flow vs brain chemistry. The addyi was originally invented as an antidepressant in male and female, it failed as an antidepressant, but women in tests of the drug said they felt more sexual zest, which led to it being studied as a Hypoactive sexual desire disorder treatment.

Comparison Between Viagra and Addyi-





Viagra Increase the Blood flow in Penis but the Addyi Boosts Chemicals in Brain for women sexual desire. Both are increases the sexual desire but the pharmacological action of the drugs is totally different.

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Dose

After approval, the United State Food and Drug Administration prescribed 100mg dose of drug should be taken once daily at bed time only. USFDA also advice if patients experienced no improvement in sexual desire within eight weeks, they should discontinue immediately.

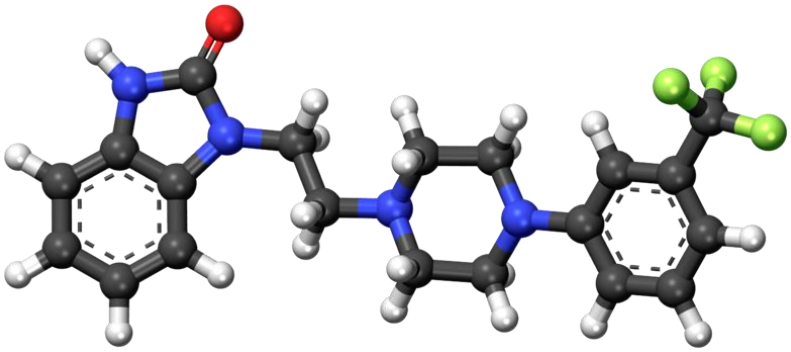
Route of Administration

Addyi is a tablet for oral administration.

Chemical Formula

$C_{20}H_{12}F_3N_4O$

Chemical Structure



Adverse Reaction of the Drug

USFDA reported the most common adverse reaction in women's is nausea, dizziness, Somnolence, fatigue, insomnia, and dry mouth. With alcohol, the drug shown low blood pressure and loss of consciousness.

Warning by Addyi

1) Do not take alcohol with or after addyi.
2) Do not take addyi, if you have lever issue.
3) Addyi is not indicated for the use of Paediatric.
4) Addyi is not indicated for the use of geriatric patient, because safety and effectiveness have not been established in geriatric patient.
5) Do not take addyi, if you take certain HIV-1 infection medicine, certain drug treated antifungal infection, certain antibiotics, certain medicine treated Hepatitis C infection.

Storage Condition

Addyi stored at room temperature between 68°F to 77°F (20°C to 25°C)

Availability

Addyi Launching in the month of October 2017 as per Sprout Pharmaceuticals statement and Addyi is available as a 100mg oval, pink, film-coated tablet. Available in bottles of 30 tablets.

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History of Addyi

A federal advisory council to the USFDA rejected the medication of flibanserin, citing an insufficient risk benefit ratio on June 2010. The council acknowledge the legitimacy of hypoactive sexual desire as a diagnosis, but manifest concern with the drugs adverse effect and inadequate evidence for efficacy, especially the drug's failure to show a statistically considerable effect on the co-primary endpoint of sexual desire. The Food and Drug Administration issued an Integrated Response circular, stating that New Drug Application could not be approved in its current form. The circular mentioned several concerns, including the failure to show a statistical effect on the co-primary endpoint of sexual desire and overlay restrictive entry criteria for two phase three trial. FDA recommended performing a new phase three trial with pinpoint restrictive entry criteria. On October 2010, Boehringer announced that it would discontinue its manufacturing of flibanserin considering the council's decision.

After Few years, the Sprout replicate to the US Food andDrug Administration's cited deficiencies and refiled the New Drug Application in 2013. The memorandum included data from a new phase three trial and several phases 1 drug to drug interaction studies but Food and Drug Administration again refuse deny the application, citing an uncertain risk-benefit ratio. In December 2013, a formal dispute proposal was filed, which having the requirements of the Food and Drug Administration for ahead studies. The application having two studies performed in healthy matter to determine if flibanserin depolarize their capability to drive and to calculate if it interferes with other biochemical pathways. The council agree to organise the new advisory committee meeting to consider whether the risk-benefit of flibanserin was favourable after this supplement data was received. Sprout requisite to refiled the NDA in the 2014.

On June 2015, the USFDA Advisory Committee, which comprise the Bone Reproductive and Urologic Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee recommended approval of the flibanserin. And then August 2015 the FDA finally approved the Addyi for the medication of Hypoactive Sexual Desire Disorder.

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