


Public Notification: U-Dream Full Night contains hidden drug ingredient

[12-18-2019] The Food and Drug Administration is advising consumers not to purchase or use U-Dream Full Night, a product promoted and sold as a sleep aid on various websites, including www.amazon.com (<http://www.amazon.com>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), and possibly in some retail stores.

FDA laboratory analysis confirmed that U-Dream Full Night contains a substance structurally similar to eszopiclone and zopiclone. Eszopiclone is the active ingredient in the FDA-approved prescription drug Lunesta, a controlled substance and a sedative-hypnotic (sleep) medicine used to treat insomnia in adults. Zopiclone is a sedative-hypnotic that has been promoted as a sleep aid in other countries but has not been approved by the FDA. Eszopiclone and zopiclone are known to cause impairment of driving and other activities that require alertness the next morning or next day after use. These ingredients may also cause dry mouth, headache, dizziness, drowsiness, memory loss, and abnormal thoughts and behavior.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at MedWatch Online Voluntary Reporting Form (<https://www.accessdata.fda.gov/scripts/medwatch/>), or;
- Download and complete the form (</media/85598/download>), then submit it via fax at 1-800-FDA-0178.

Note: This notification is to inform the public of a growing trend of dietary supplements or conventional foods with hidden drugs and chemicals. These products are typically promoted for sexual enhancement, weight loss, and body building and are often represented as being “all natural.” FDA is unable to test and identify all products marketed as dietary supplements that have potentially harmful hidden ingredients. Consumers should exercise caution before purchasing any product in the above categories.

Please refer to the links below for more information:

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