

RECALL

NOTIFICATION

FDA PUBLICATION DATE: February 16, 2021

DRUG NAME: Adam's Secret Extra Strength 1500 and Adam's Secret Extra Strength 3000 capsules

COMPANY: Adamssecret.co

RFASON: Product contains

undeclared sildenafil

and/or tadalafil.

February 17, 2021

COM-2021-022

Dear Consumers,

PharmPix is committed to the health and well-being of patients. For this reason, we are notifying you that on February 16, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary recall for all lots of Adam's Secret Extra Strength 1500 and Adam's Secret Extra Strength 3000 capsules, manufactured by Adamssecret.co.

Affected product:

| Product description | Lot # |
|---|----------|
| Adam's Secret Extra Strength 1500 and Adam's Secret Extra Strength 3000 capsules | All lots |

This recall has been initiated after an FDA laboratory analysis found the product to contain undeclared sildenafil and/or tadalafil. Sildenafil and tadalafil are ingredients in FDA approved products for the treatment of male erectile dysfunction in the family of drugs known as phosphodiesterase (PDE-5) inhibitors. The presence of sildenafil and/or tadalafil in Adam's Secret Extra Strength products makes them unapproved new drugs for which the safety and efficacy have not been established and therefore subject to recall. Consumers with underlying medical issues who take Adam's Secret Extra Strength 1500 or Adam's Secret Extra Strength 3000 capsules with undeclared sildenafil and tadalafil may experience serious health risks. For example, PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin), lowering blood pressure to dangerous levels that may be life-threatening. Consumers with diabetes, high blood pressure, or heart disease often take nitrates.

The product is marketed as a dietary supplement for male sexual enhancement and is packaged in blister foil sheets and a box containing 10 capsules. Adam's Secret Extra Strength 1500 and 3000 were distributed via the internet at www.adamssecret.com nationwide in the USA.





Consumers required actions(s):

- Identify if the product is in inventory and immediately stop using and return to the place of purchase.
- Contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

<u>Contact information</u>: For further details, contact Adamssecret.co by e-mail address <u>adamssecret.co@gmail.com</u> or mail at <u>-</u>29-31 Industrial Ave. Fairview, NJ 07022.

Remember, you can report adverse events or side effects at <u>MedWatch: The FDA Safety</u> <u>Information and Adverse Event Reporting Program</u> by any of the following ways:

- Complete and submit the <u>MedWatch Online Voluntary Reporting Form</u> online.
- <u>Download</u> the FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at:

- <u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/adamssecretco-issues-</u>voluntary-nationwide-recall-adams-secret-extra-strength-1500-and-3000-capsules
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: <u>https://www.pharmpix.com/providers/.</u>

Regards,

PharmPix Clinical Department

Reference:

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ACCREDITED

Pharmacy Benefit



U.S. Food and Drug Administration. (2021). Adamssecret.co Issues Voluntary Nationwide Recall of Adam's Secret Extra Strength 1500 and 3000 Capsules Due to Presence of Undeclared Sildenafil and/or Tadalafil. Retrieved February 17, 2021, from <u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/adamssecretco-issues-voluntary-nationwide-recall-adams-secretextra-strength-1500-and-3000-capsules</u>