

COMPANY ANNOUNCEMENT

Volt Candy Issues Voluntary Nationwide Recall of PrimeZen Black 6000 Capsules Due to Presence of Sildenafil and Tadalafil

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

February 13, 2023

FDA Publish Date:

February 13, 2023

Product Type:

Drugs

Reason for Announcement:

Product contains undeclared tadalafil and sildenafil

Company Name:

Volt Candy

Brand Name:

PrimeZEN

Product Description:

PrimeZEN Black 6000 male enhancement capsules

Company Announcement

FOR IMMEDIATE RELEASE – 2/13/2023 – Pomona, California, Volt Candy is voluntarily recalling one lot of PrimeZen Black 6000, 2000 mg capsule, to the **consumer** level. FDA analysis has found PrimeZen Black 6000 capsules to be tainted with sildenafil & tadalafil. Sildenafil and tadalafil are phosphodiesterase (PDE-5) inhibitors found in FDA-approved

products for the treatment of male erectile dysfunction. The presence of sildenafil, tadalafil in PrimeZen Black 6000 capsules renders them unapproved drugs for which safety and efficacy have not been established and, therefore, subject to recall.

Risk Statement: PrimeZen Black 6000 capsules containing sildenafil and tadalafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may cause a significant drop in blood pressure that may be life threatening. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Among the adult male population who are most likely to use these products, adult males who use nitrates for cardiac conditions are most at risk from these products. Volt Candy has not received reports of state adverse events or injuries to date.

Product was distributed Nationwide to consumers online at the website info@voltcandy.com. PrimeZen Black 6000 is marketed as a dietary supplement for male enhancement and is packaged in a blister card with one capsule, UPC code: 728175521891. The affected PrimeZen Black 6000 includes the following lot number [NPINPB 1003] with an expiration date of 08/16/2025. The product can be identified by the card color in black with the name on it PrimeZen Black 6000. See picture of product below.

Volt Candy is notifying their online customers by email and is arranging for return of all recalled products. Consumers or those with product in their possession should stop using and return the affected product PrimeZen Black 6000, lot number [NPINPB 1003] Expiration date 08/16/2025 to this address:

Volt Candy
324 S. Diamond Bar Blvd
#212
Diamond Bar, CA 91765

Consumers with questions regarding this recall can contact Volt Candy by e-mail info@voltcandy.com (<mailto:info@voltcandy.com>) on weekdays between 9am-5pm PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm ([/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda](http://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda))

- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm ([/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting](http://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting)) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

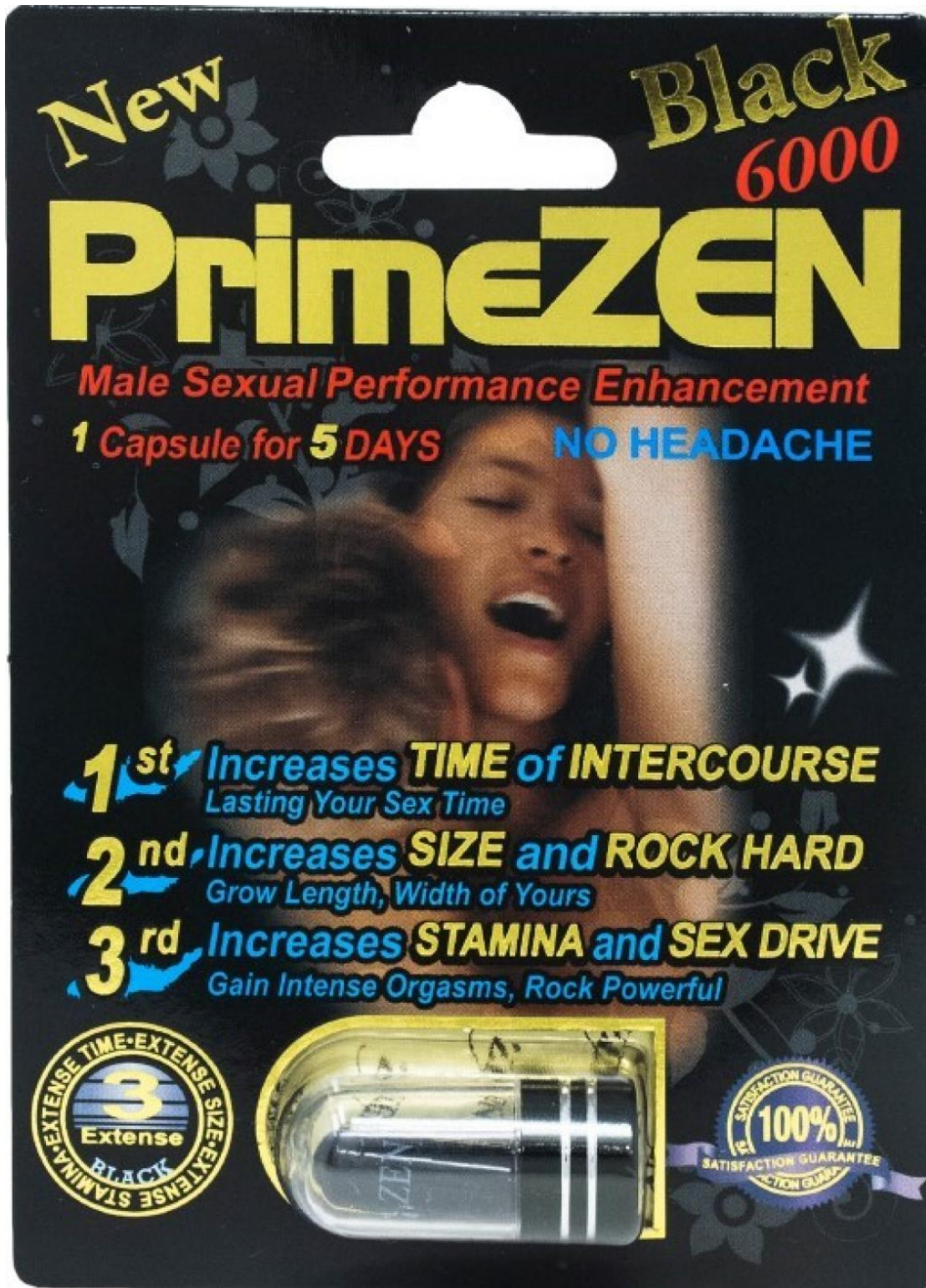
Company Contact Information

Consumers:

Volt Candy

✉ info@voltcandy.com (<mailto:info@voltcandy.com>)

Product Photos





[!\[\]\(bd1a142de767a21e5362c595f844a4ff_img.jpg\) More Recalls, Market Withdrawals, & Safety Alerts \(/safety/recalls-market-withdrawals-safety-alerts\)](#)

