Avkare Issues Voluntary Nationwide Recall of Sildenafil 100 mg Tablets and Trazodone 100 mg Tablets Due to Product Mix-Up

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Avkare has posted a lot recall of Sildenafil 100 mg tablets and Trazodone 100 mg tablets.

About this Recall:
Avkare is voluntarily recalling 1 lot of sildenafil 100 mg tablets and 1 lot of trazodone 100 mg tablets to the consumer level. These products have been recalled due to a product mix-up of the listed 2 separate products inadvertently packaged together during bottling at a third party facility.

What this means to you:
Unintented intake of sildenafil may pose serious health risks to those with underlying medical issues. For example, sildenafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) lowering blood pressure to dangerous levels. Patients with diabetes, high blood pressure, or heart disease often take nitrates.

Unintended intake of trazodone may result in adverse health consequences such as somnolence/sedation, dizziness, constipation, and blurred vision. These adverse events may be more concerning in elderly patients due to an increased risk for falls and driving impairment. To date, Avkare has not received any reports of adverse events related to this recall.

Sildenafil, the active ingredient in Viagra®, which is a phosphodiesterase-5 (PDE-5) inhibitor, is used for the treatment of erectile dysfunction (ED) and is packaged in 100 count bottles (NDC 42291-748-01). Trazodone is indicated for the treatment of major depressive disorder and is packaged in 1,000 count bottles (NDC 42291-834-10). The recalled lots of sildenafil 100 mg tablet (lot 36884 with an expiration date of 03/2022) and trazodone hydrochloride 100 mg tablet (lot 36783 with an expiration date of 06/2022) were distributed to distributors and wholesalers, and then further distributed nationwide. Avkare has notified its distributors and customers and is arranging for return of all recalled product.

Consumers with questions regarding this recall can contact Avkare at 1-855-361-3993 Monday through Friday (8 am – 4 pm CST). Consumers should contact their physician or healthcare provider (HCP) if they have experienced any problems that may be related to taking or using these drug products.

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
- Regular Mail or Fax: Download form 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 United States (US) Food and Drug Administration (FDA).

For more information regarding this FDA Recall Notification, please refer to the FDA website:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/avkare-issues-voluntary-nationwide-recall-sildenafil-100mg-tablets-and-trazodone-100mg-tablets-due

FDA contact information for reporting adverse events/quality complaints can be reached online at
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.