RXADVANCE
136 Turnpike Rd
Southborough, MA 01772

Sildenafil Tablets and Trazodone Tablets Recall Alert

Date of Notice: 12/09/2020

Brief Description of Recall Alert

AvKARE, Pulaski, TN is voluntarily recalling one lot of sildenafil 100mg tablets and one lot of trazodone 100mg tablets to the consumer level. These products have been recalled due to a product mix-up of the listed two separate products inadvertently packaged together during bottling at a 3rd party facility.

Unintentional consumption of sildenafil may pose serious health risks to consumers 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. Consumers 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 a subsequent 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 PDE-5 inhibitor, is used for the treatment of erectile dysfunction and is packaged in 100 count bottles, NDC 42291-748-01. Trazodone hydrochloride is indicated for the treatment of major depressive disorder and packaged in 1,000 count bottles, NDC 42291-834-10. The affected 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 our distributors and wholesalers, and then further distributed nationwide.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
sildenafil 100 mg tablet	42291-748-01	36884	03/2022
trazodone hydrochloride 100 mg tablet	42291-834-10	36783	06/2022

Prescriber Information

Adverse reactions or issues experienced with the use of this drug 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

Member Information

AvKARE has notified its distributors and customers and is arranging for return of all recalled product of the listed lots. Distributors that have any of the subject product which is being recalled should contact Customer Service at AvKARE at 1-855-361-3993 or email customerservice@avkare.com to arrange for the return of the product.

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

RxAdvance Response

RxAdvance recommends that you speak to your doctor and local pharmacy about any concerns in regards to this recall.