December 10, 2020 **COM-2020-094**

RECALL NOTIFICATION

FDA PUBLICATION DATE: December 9, 2020

DRUG NAME:

- **Sildenafil 100 mg tablets**
- **Trazodone 100mg tablets**

COMPANY: AvKARE

REASON: Product mix-up

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date information on drug safety. For this reason, we are notifying you that on December 9, 2020, the U.S. Food and Drug Administration (FDA) published a voluntary recall for one lot of **Sildenafil 100mg tablets and Trazodone 100mg tablets** by AvKARE company.

NDC	Product description	Lot #	Expiration Date
42291-0748-01	**Sildenafil 100mg Tablets, USP**	36884	03/2022
42291-0834-10	**Trazodone 100mg Tablets, USP**	36783	06/2022

The voluntary recall is due to a product mix-up of the listed different products inadvertently packaged together. Unintended intake of both products may be associated with adverse drug events or drug-drug interactions. Sildenafil may interact with nitrates causing lower blood pressure, and Trazodone may cause sedation, dizziness, constipation, and blurred vision. The elderly population has an increased risk for falls or driving impairment. Up to date, no adverse events have been reported to the manufacturer.

<u>Pharmacy required actions(s):</u>

- Identify if the product is in inventory and immediately stop dispensing it.

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- Advise patients to contact their physician or healthcare provider if they have experienced any problems related to using the recalled products.

Contact information:

- Contact Customer Service at AvKARE at 1-855-361-3993 or email customerservice@avkare.com
- For questions, contact AvKARE at 1-855-361-3993 Monday- Friday (8 am – 4 pm CST).

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

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download 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:

- FDA Drug Recall web page: https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls

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

Regards,

PharmPix Clinical Department

Reference:

U.S. Food and Drug Administration. (2020). AvKARE Issues Voluntary Nationwide Recall of Sildenafil 100mg Tablets and Trazodone 100mg Tablets Due to Product Mix-Up. Retrieved on December 10, 2020 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/avkare-issues-voluntary-nationwide-recall-sildenafil-100mg-tablets-and-trazodone-100mg-tablets-due?utm_medium=email&utm_source=govdelivery

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