

## COMPANY ANNOUNCEMENT

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

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:**

December 09, 2020

**FDA Publish Date:**

December 09, 2020

**Product Type:**

Drugs

**Reason for Announcement:**

Due to product mix-up

**Company Name:**

AvKare

**Brand Name:**

AvKare

**Product Description:**

Sildenafil 100 mg tablets and Trazodone 100mg tablets

## Company Announcement

AvKARE, Pulaski, TN is voluntarily recalling one lot of Sildenafil 100 mg 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.

Product	Lot	Expiration date	Bottle count	NDC Number
Sildenafil Tablets, USP	36884	03/2022	100	42291-748-01
Trazodone Tablets, USP	36783	06/2022	1000	42291-834-10

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 1000 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.

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](mailto:customerservice@avkare.com) (mailto: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.

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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</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:

Customer Service at AvKARE

☎ 1-855-361-3993

✉ [customerservice@avkare.com](mailto:customerservice@avkare.com) (mailto:customerservice@avkare.com)

### Media:


Clifton Stanfill

☎ 931-908-2192

## Product Photos







NDC 42291-834-10

## TraZODONE Hydrochloride Tablets USP

100 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

1000 Tablets
Rx Only

**Each tablet contains 100 mg TrazODONE hydrochloride, USP.**

**Usual Dosage:** See package insert for full prescribing information.


Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

Manufactured for:  
**AvKARE, Inc.**  
 Pulaski, TN 38478

Mfg. Rev. B 3/2016 AV Rev. 04/19 (P)



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