



Date: October 9, 2026



URGENT: Voluntary Drug Recall Notice

Re: Fludrocortisone Acetate 0.1mg

Dear Valued Customer,

AvKARE is initiating a Voluntary Class 2 Recall to the RETAIL LEVEL. This recall has been initiated due to an "Out of Spec" finding of Total Impurities. There is no indication that this product is a Health Hazard to the user.

This recall is being carried out with the knowledge of the US Food and Drug Administration. Further use of this product should immediately cease. The below marketed product is subject to the recall. This recall is to the Retail Level Only.

Product Description	NDC	Initial Ship Dates	Lot & Expiration	Quantity to Return
Fludrocortisone Acetate 0.1mg	50268-330-15	7/15/2025	48353 10/31/2026	
		To 4/28/26		

Please examine your inventory to determine if you have any of the product listed above. See enclosed product label for ease in identifying the product at the retail level. If so, immediately discontinue use and remove it from active inventory. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

To start the recall return process, please visit <https://www.avkare.com/recall>. Electronically submit your response by selecting Electronic Recall Form. Alternatively, you may complete and fax the downloaded form to 931-292-6229 or email to recalls@avkare.com.

Once you submit your response, we will send you a Return Authorization Form (RMA) and shipping label to return your affected product. Also, include a copy of the letter in your return package. **Please use the shipping label provided.** Credit will be issued when the product is returned and received at our warehouse. Please return any recalled product that was purchased from AvKARE to the following address:

**R&S Northeast LLC
194 American Ave
Glasgow, KY 42141**

If you have any questions on this matter, please contact us, Monday through Friday 8am to 5 pm CST. We regret any inconvenience that this may cause.

Sincerely,
Bonnie Gray -Director of Quality
(855) 628-5273 ext. 2406
bgray@avkare.com

Crystal Oliver -Customer Service Rep.
(931) 908-2199
coliver@avkare.com

Wholesaler/DC:
Facility Name:
Facility DEA #:
Facility Address:
Contact Name:
Contact Number:
Fax/Email to send RA:



NDC 50268-330-15

**Fludrocortisone
Acetate Tablets, USP**

0.1 mg

Rx Only

50 Tablets (5 X 10) Unit Dose



5026833015

NDC 50268-330-15

**Fludrocortisone
Acetate Tablets, USP**

0.1 mg

Rx Only

50 Tablets (5 X 10) Unit Dose



5026833015

Each tablet contains Fludrocortisone acetate, USP... 0.1 mg

USUAL DOSAGE: See accompanying outsert for complete prescribing information.

Warning: Potent drug

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Avoid excessive heat.

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

Manufactured for:
AvKARE
Pulaski, TN 38478
www.avkare.com



Mfg. Rev. 08-2024-03

AV Rev. 05/25 (M)