



Date: May 14, 2025

Updated: SUB-RECALL
URGENT: Voluntary Drug Recall Notice

Re: Ophthalmic Recall

Dear Valued Customer,

We are assisting BRS Analytical Service, LLC. In a Voluntary Recall. **This has changed to the RETAIL LEVEL ONLY.** This recall has been initiated due to manufacturing cGMP deviations identified during an audit by FDA. Health Hazard to the user is unknown, cGMP deviations may lead to products of unacceptable quality, and it is not possible to rule out patient risks resulting from use of these products. The below marketed products are subject to the recall.

- **NDC# 50268-043-15 Artificial Tears Ophthalmic Solution**
- **NDC# 50268-066-15 Carboxymethylcellulose Sodium Ophthalmic Gel 1%**
- **NDC# 50268-068-15 Carboxymethylcellulose Sodium Ophthalmic Solution**
- **NDC# 50268-126-15 Lubricant Eye Drops Solution**
- **NDC# 50268-678-15 Polyvinyl Alcohol Ophthalmic Solution**

This recall is being carried out with the knowledge of the US Food and Drug Administration. Further use of this product should immediately cease.

These items were first shipped May 26, 2023, until April 21, 2025

Please examine your inventory to determine if you have any of the lot's listed below. If so, immediately discontinue use and remove it from active inventory.

NDC & Product Description			NDC & Product Description		
NDC 50268-043-15 Artificial Tears Ophthalmic Solution		Quantity to Return	NDC 50268-043-15 Artificial Tears Ophthalmic Solution		Quantity to Return
Lot # & Expiration Date			Lot # & Expiration Date		
Lot: 0126	Exp. 10/26/25		Lot: 0168	Exp. 06/06/26	
Lot: 0127	Exp. 10/30/25		Lot: 0169	Exp. 06/10/26	
Lot: 0128	Exp. 11/02/25		Lot: 0170	Exp. 06/13/26	
Lot: 0129	Exp. 11/06/25		Lot: 0193	Exp. 10/07/26	
Lot: 0162	Exp. 05/09/26		Lot: 0194	Exp. 10/10/26	
Lot: 0163	Exp. 05/14/26		Lot: 0195	Exp. 10/14/26	
Lot: 0164	Exp. 05/20/26		Lot: 0196	Exp. 10/17/26	
Lot: 0165	Exp. 05/23/26		Lot: 0197	Exp. 10/21/26	
Lot: 0166	Exp. 05/29/26		Lot: 0198	Exp. 10/24/26	
Lot: 0167	Exp. 06/03/26		Lot: 0199	Exp. 10/30/26	

We request that you complete "Quantity to Return" section and the Customer information block below. Please fax to 931-292-6229 or email customerservice@avkare.com. Even if the quantity is zero.



NDC & Product Description			NDC & Product Description		
NDC 50268-066-15 Carboxymethylcellulose Sodium Ophthalmic Gel 1%			NDC 50268-066-15 Carboxymethylcellulose Sodium Ophthalmic Gel 1%		
Lot # & Expiration Date		Quantity to Return	Lot # & Expiration Date		Quantity to Return
Lot: 0114	Exp. 09/04/25		Lot: 0116	Exp. 09/10/25	
Lot: 0115	Exp. 09/06/25		Lot: 0207	Exp. 12/05/26	

NDC & Product Description			NDC & Product Description		
NDC# 50268-068-15 Carboxymethylcellulose Sodium Ophthalmic Solution 0.5%			NDC# 50268-068-15 Carboxymethylcellulose Sodium Ophthalmic Solution 0.5%		
Lot # & Expiration Date		Quantity to Return	Lot # & Expiration Date		Quantity to Return
Lot: 0103	Exp. 04/26/25		Lot: 0155	Exp. 04/08/26	
Lot: 0104	Exp. 05/03/25		Lot: 0156	Exp. 04/08/26	
Lot: 0108	Exp. 06/29/25		Lot: 0157	Exp. 04/11/26	
Lot: 0109	Exp. 07/18/25		Lot: 0160	Exp. 04/26/26	
Lot: 0110	Exp. 08/17/25		Lot: 0180	Exp. 08/08/26	
Lot: 0111	Exp. 08/22/25		Lot: 0181	Exp. 08/12/26	
Lot: 0112	Exp. 08/27/25		Lot: 0182	Exp. 08/18/26	
Lot: 0113	Exp. 09/18/25		Lot: 0183	Exp. 08/21/26	
Lot: 0125	Exp. 10/23/25		Lot: 0184	Exp. 08/26/26	
Lot: 0130	Exp. 11/09/25		Lot: 0185	Exp. 09/04/26	
Lot: 0131	Exp. 11/14/25		Lot: 0186	Exp. 09/09/26	
Lot: 0132	Exp. 11/27/25		Lot: 0187	Exp. 09/13/26	
Lot: 0133	Exp. 11/30/25		Lot: 0189	Exp. 09/21/26	
Lot: 0134	Exp. 12/05/25		Lot: 0190	Exp. 09/25/26	
Lot: 0135	Exp. 12/11/25		Lot: 0191	Exp. 09/28/26	
Lot: 0136	Exp. 12/14/25		Lot: 0192	Exp. 10/02/26	
Lot: 0137	Exp. 01/02/26		Lot: 0208	Exp. 12/11/26	
Lot: 0139	Exp. 01/15/26		Lot: 0209	Exp. 12/16/26	
Lot: 0140	Exp. 01/19/26		Lot: 0212	Exp. 01/15/27	
Lot: 0141	Exp. 01/25/26		Lot: 0213	Exp. 01/21/27	
Lot: 0151	Exp. 03/18/26		Lot: 0214	Exp. 01/24/27	
Lot: 0152	Exp. 03/21/26		Lot: 0215	Exp. 02/02/27	
Lot: 0153	Exp. 03/25/26		Lot: 0216	Exp. 02/04/27	
Lot: 0154	Exp. 03/28/26		Lot: 0224	Exp. 03/27/27	

We request that you complete "Quantity to Return" section and the Customer information block below. Please fax to 931-292-6229 or email customerservice@avkare.com. Even if the quantity is zero.



NDC & Product Description			NDC & Product Description		
NDC# 50268-126-15 Lubricant Eye Drops Solution			NDC# 50268-126-15 Lubricant Eye Drops Solution		
Lot # & Expiration Date		Quantity to Return	Lot # & Expiration Date		Quantity to Return
Lot: 0117	Exp. 09/20/25		Lot: 0201	Exp. 11/10/26	
Lot: 0118	Exp. 09/25/25		Lot: 0202	Exp. 11/13/26	
Lot: 0119	Exp. 09/27/25		Lot: 0203	Exp. 11/18/26	
Lot: 0121	Exp. 10/05/25		Lot: 0204	Exp. 11/21/26	
Lot: 0161	Exp. 05/01/26		Lot: 0205	Exp. 11/25/26	
Lot: 0171	Exp. 06/18/26		Lot: 0206	Exp. 12/02/26	
Lot: 0172	Exp. 06/24/26		Lot: 0219	Exp. 02/24/27	
Lot: 0174	Exp. 07/01/26		Lot: 0221	Exp. 03/02/27	
Lot: 0175	Exp. 07/08/26		Lot: 0222	Exp. 03/05/27	
Lot: 0200	Exp. 11/05/26				
NDC & Product Description			NDC & Product Description		
NDC# 50268-678-15 Polyvinyl Alcohol Ophthalmic Solution			NDC# 50268-678-15 Polyvinyl Alcohol Ophthalmic Solution		
Lot # & Expiration Date		Quantity to Return	Lot # & Expiration Date		Quantity to Return
Lot: 0120	Exp. 10/02/25		Lot: 0147	Exp. 02/21/26	
Lot: 0122	Exp. 10/09/25		Lot: 0148	Exp. 02/27/26	
Lot: 0123	Exp. 10/12/25		Lot: 0149	Exp. 03/04/26	
Lot: 0124	Exp. 10/16/25		Lot: 0150	Exp. 03/11/26	
Lot: 0138	Exp. 10/08/26		Lot: 0158	Exp. 04/15/26	
Lot: 0142	Exp. 12/09/26		Lot: 0159	Exp. 04/22/26	
Lot: 0143	Exp. 02/01/26		Lot: 0176	Exp. 07/24/26	
Lot: 0144	Exp. 02/07/26		Lot: 0177	Exp. 07/28/26	
Lot: 0145	Exp. 02/12/26		Lot: 0178	Exp. 07/31/26	
Lot: 0146	Exp. 02/15/26		Lot: 0179	Exp. 08/05/26	

We request that you complete "Quantity to Return" section and the Customer information block below. Please fax to 931-292-6229 or email customerservice@avkare.com. Even if the quantity is zero.



IF YOU HAVE PREVIOUSLY SENT A REQUEST FOR A RETURN AUTHORIZATION, PLEASE ALLOW EXTRA TIME FOR THE RESPONSE.

Instructions: Please check your inventory for the product listed above. If you have it, stop using it immediately and remove it from stock.

Complete the "Quantity to Return" section above and the customer information below, even if you're returning **zero**. Send the completed form by fax to 931-292-6229 or email it to customerservice@avkare.com.

After we receive your response, we'll send you a Return Authorization Form (RMA) and a shipping label. Include a copy of this letter in your return package and use the provided label. We'll issue credit once the product is returned and received.

Return Address:
R&S Northeast LLC
8407 Austin Tracy Rd
Fountain Run, KY 42133

If you have any questions, please contact us. We apologize for any inconvenience this may cause.

Sincerely,
Renee Malone -Director of Quality
(931) 908-0014
rmalone@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: