

Memorandum

To: Gold Coast Health Plan Providers

From: Lily Yip, Pharm.D., MBA, APh, CDCES, BCACP, CPHQ, Director of Pharmacy

Re: **FDA Drug Recall/Voluntary Market Withdrawal**

Date: Oct. 6, 2026

This is a notification regarding multiple Food and Drug Administration (FDA) drug recalls / voluntary manufacturer withdrawals that may impact Gold Coast Health Plan (GCHP) members. Detailed information regarding each affected product is provided below.

Recall / Withdrawal #1

Drug: Ranolazine ER 1,000 mg tablet

Manufacturer: Ajanta Pharma USA, Inc.

Reason for Recall / Withdrawal: Failed dissolution specifications

Effective Date: Sept. 17, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Ranolazine	ER 1,000 mg	Tablet	27241-0126-02	DJ25134	Nov. 30, 2028

FDA Recall / Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=222834>

Manufacturer Communication: 1-855-664-7744 or email pv.ap@navatiopharma.com.

Recall / Withdrawal #2

Drug: Carboxymethylcellulose Sodium Ophthalmic Solution 0.5%

Manufacturer: AvKare

Reason for Recall / Withdrawal: Lack of assurance of sterility.

Effective Date: Sept. 14, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Carboxymethylcellulose 0.5% Sodium		Ophthalmic solution	50268-0068-15	3245	Mar. 2027
				3260	May 2027
				3298	Jun. 2027
				3299	Jun. 2027
				3300	Jun. 2027
				3301	Jul. 2027
				3302	Jul. 2027

3305	Jul. 2027
3306	Jul. 2027

FDA Recall/Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=222576>

Manufacturer Communication: 1- 855-628-5273 6 a.m. - 3 p.m. PST Monday - Friday or email drugsafety@avkare.com.

Clinical Considerations

Providers should:

- Review patient records to identify individuals receiving affected product(s).
- Evaluate patients for potential clinical impacts related to the recall or withdrawal.
- Discontinue use of affected product(s) as appropriate.
- Transition patients to an appropriate alternative therapy when clinically indicated.
- Monitor patients for potential adverse events and/or treatment interruptions.

Member Notification

GCHP has identified and notified potentially affected members by letter regarding this drug recall / withdrawal.

Additional Information

For additional details regarding this drug recall/withdrawal, please refer to:

- [FDA Drug Safety Communications](#)
- [FDA Recalls, Market Withdrawals, & Safety Alerts](#)
- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)
- [The FDA Weekly Enforcement Report](#)

For additional questions, please email GCHP Pharmacy Services Department at Pharmacy@goldchp.org.