

**URGENT DRUG SAFETY  
ALERT**

June 15, 2020

Dear Patient,

The purpose of this letter is to inform you that Fresenius Medical Care North America is initiating an *alert* of three (3) lots of Calcium Acetate Gelcaps. It was discovered that gelcaps with different logos (“SANDOZ 576” and “FMCNA 667”) were observed to be in the same bottle (Lot # 281289, Exp. 06/2024). Two additional lots are affected, Lot # 283851, Exp. 07/2024 and Lot # 283852, Exp. 07/2024.

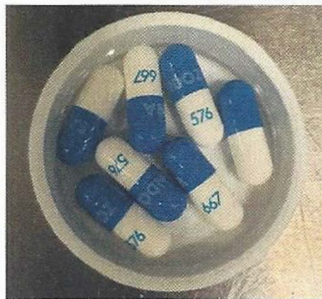
**Affected Products**

Product Name	Lot Number	Expiration Date	NDC Number
Calcium Acetate Gelcaps, 667mg	281289	06/2024	0781-2081-02
	283851	07/2024	
	283852	07/2024	

**Problem  
Description**

**Gelcaps with differing logos**

The gelcaps within the bottles encapsulate the same formulation of Calcium Acetate at the same dosage 667mg and are composed of the same material and strength. The only difference is the number and logo marking upon the gelcaps (i.e. “SANDOZ 576” and “FMCNA 667”).



**Hazard Involved**

The assessed risk to patients is low. However, in rare cases, patients may be confused and stop taking the gelcaps. If patients stop taking their prescribed dosage, they could experience elevated phosphate levels. Additionally, patients could mistake the SANDOZ 576 marking to represent dosage; by taking additional gelcaps to compensate, patients may experience mild symptoms of nausea, constipation, and fatigue.

**Customers may continue to take the medication as prescribed. This is for information purposes only and no action is needed.**



**Sandoz Inc.**  
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**Further  
Information**

Thank you for your cooperation. If you have additional questions, please contact Sandoz at (800) 525-8747.

Please report any adverse reactions by calling Sandoz at (800) 525-8747. Customer service agents are available from 8:00AM to 5:00PM (EST), Monday-Friday. Adverse events can also be reported to FDA online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).

Thank you again for your support with this alert.

Sincerely,  
**SANDOZ INC.**

Emma Harrington  
Head, Novartis Country Quality US

**Enclosure:**  
Fresenius Medical Urgent Drug Safety Alert