July 1, 2020

Urgent: Sandoz Inc. is Initiating a Drug Safety Alert for three lots of Calcium Acetate Gelcaps

Dear ASD Healthcare Customer:

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. The affected lot information is listed below.

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”).

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 addition gelcaps to compensate, patients may experience mild symptoms of nausea, constipation, and fatigue.

Please Note: This is not a recall and no product should be returned.

Customers may continue to take this product as prescribed.

Sandoz Inc. provided the following affected NDC information:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Lot Number</th>
<th>Expiration Date</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Acetate Gelcaps, 667mg</td>
<td>281289</td>
<td>06/2024</td>
<td></td>
</tr>
<tr>
<td></td>
<td>283851</td>
<td>07/2024</td>
<td>0781-2081-02</td>
</tr>
<tr>
<td></td>
<td>283852</td>
<td>07/2024</td>
<td></td>
</tr>
</tbody>
</table>

If you have any questions or concerns, please contact ASD Healthcare’s customer service at 800.746.6273.
June 15, 2020

Dear Wholesaler,

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.

<table>
<thead>
<tr>
<th>Affected Products</th>
<th>Lot Number</th>
<th>Expiration Date</th>
<th>NDC Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Acetate Gelcaps, 667mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>281289</td>
<td>06/2024</td>
<td></td>
</tr>
<tr>
<td></td>
<td>283851</td>
<td>07/2024</td>
<td></td>
</tr>
<tr>
<td></td>
<td>283852</td>
<td>07/2024</td>
<td></td>
</tr>
</tbody>
</table>

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 this product as prescribed.
Wholesaler Action

Please complete the enclosed Business Reply Card confirming your receipt of this letter. The Business Reply Card can be returned by fax or mail. Returning the card promptly will prevent you from receiving a repeat notice.

Please also notify your direct customers of this important safety information by providing them with a copy of the enclosed Dear Pharmacy and Dear Patient letters.

THIS IS NOT A RECALL AND NO PRODUCT SHOULD BE RETURNED.

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.

Thank you again for your support with this alert.

Sincerely,

SANDOZ INC.

[Signature]

Emma Harrington
Head, Novartis Country Quality US

Enclosures:
Sandoz Inc. Pharmacy Letter
Sandoz Inc. Patient Letter
Fresenius Medical Urgent Drug Safety Alert
Sandoz Business Reply Card
*** Urgent Drug Safety Alert ***

Calcium Acetate Gelscaps, 667mg
Gelscaps with differing logos
FA-2020-10-C_REV A

Dear Healthcare Professional,

The purpose of this letter is to inform you that Fresenius Medical Care North America is initiating an alert of three (3) batches of Calcium Acetate Gelscaps, **Part Number: 6402-3, 667mg; Batch Numbers: 281289, 283851, and 283852**. It was discovered that gelscaps with different logos (SANDOZ 576 & FMCNA 667) were observed to be in the same bottle (batch number 281289, exp 06/2024).

The gelscaps within the bottles encapsulate the same formulation of calcium acetate at the same dosage (667mg) and are composed of the same material. The only difference is the number and logo marking upon the gelscaps (SANDOZ 576 & FMCNA 667).

**Product Information**

<table>
<thead>
<tr>
<th>Product name</th>
<th>Calcium Acetate Gelscaps, 667mg (Generic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC Number</td>
<td>0781-2081-02</td>
</tr>
<tr>
<td>Part Number</td>
<td>6402-3</td>
</tr>
<tr>
<td>Lot/Expiration Date</td>
<td>281289 (06/2024), 283851 (07/2024), and 283852 (07/2024)</td>
</tr>
</tbody>
</table>

Fresenius Medical Care North America
Corporate Headquarters: 920 Winter Street  Waltham, MA 02451  (781) 699-9000

6916_01_07AS_V1.1

Pg. 1 of 2
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 this product as prescribed.

This is a Safety Alert only. No product is being asked for return.

We apologize for any inconvenience and appreciate your attention and assistance.

Sincerely,

[Signature]

Joseph P. Winslow
SVP Product Quality
<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>NDC #</th>
<th>LOT #</th>
<th>EXPIRATION DATE</th>
<th>BOTTLES ON HAND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Acetate Gelcaps, 667mg</td>
<td>0781-2081-02</td>
<td>281289</td>
<td>06/2024</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>283851</td>
<td>07/2024</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>283852</td>
<td>07/2024</td>
<td></td>
</tr>
</tbody>
</table>

Your timely response to this drug safety alert notification is requested. Please fill out, tear off this reply card and mail, email to Sandoz6916@stericycle.com or fax to 1-888-628-0726 within five (5) business days, even if you do not have the impacted product. Thank you.

Signature __________________________ Title __________________________

Name __________________________ Phone # __________________________