URGENT PRODUCT RECALL

September 01, 2016

Dear Director of Pharmacy:

Problem Description

Baxter Healthcare Corporation has been notified that Sandoz, the supplier of the Transderm Scop® (Scopolamine) TDS, 1.5mg Patch, is recalling the below lot numbers in response to increased reports of damaged product that may alter the predicted release of scopolamine following transdermal application. Our records indicate that Baxter Healthcare distributed the affected lots between 2/24/2016 and 7/27/2016. Please see the enclosed Sandoz Urgent Drug Recall notification dated 08/25/2016.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>NDC (24-count)</th>
<th>Lot Number</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transderm Scop® (Scopolamine) TDS, 1.5mg (NDC 10019-553-88)</td>
<td>10019-553-02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FV5908</td>
<td>FX1520</td>
<td>GB4910</td>
<td>06/2018</td>
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<td>GC4210</td>
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<td>GE1927</td>
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<td></td>
<td></td>
<td>GF6017</td>
<td>12/2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GH6065</td>
<td>01/2019</td>
</tr>
</tbody>
</table>

Hazard Involved

Overexposure to scopolamine may cause patients or caregivers handling the damaged product to experience increased side effects.

Actions to be taken if product was purchased directly from Baxter

1. Locate and remove all affected product lots from your facility. The product code, lot, and expiration date can be found on the individual product or shipping carton.

2. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.

3. Complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to fcrc@baxter.com. Returning the Baxter customer reply form promptly will prevent you from receiving repeat notices.

4. If you distribute this product to other facilities or departments within your institution (e.g., Pharmacy, ER, ICU, NICU, PICU), please forward a copy of this communication to them.

5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a retail-level recall of the affected product lots that you distributed to customers.
Action to be taken if product was purchased from a distributor

1. Locate and remove all affected product lots from your facility. The product code, lot, and expiration date can be found on the individual product or shipping carton.

2. Contact Baxter Healthcare Center for Service to arrange for return and credit. The Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.

3. Please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

Further information and support

For general questions regarding this communication, contact Baxter Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

We appreciate your immediate attention and cooperation.

Sincerely,

[Signature]

Merle Goddard
Senior Director, Quality
Baxter Healthcare Corporation

cc: Director of Materials Management

Enclosure: Sandoz Urgent Drug Recall Letter
Baxter Customer Reply Form
August 25, 2016

URGENT DRUG RECALL

Transderm Scop® (Scopolamine) TDS, 1.5mg, 24 Count (Patches)

Dear Valued Customer:

The purpose of this letter is to inform you that Sandoz Inc. ("Sandoz") is initiating a Voluntary Recall of seven (7) lots of Transderm Scop® (Scopolamine) TDS, 1.5mg, 24 Count (Patches). These seven (7) lots are being recalled in response to increased reports of damaged product that may alter the predicted release of scopolamine following transdermal application. Overexposure to scopolamine may cause patients or caregivers handling the damaged product to experience increased side effects.

This Voluntary Recall is being conducted to the Retail Level with the knowledge of the Food and Drug Administration. All locations which received direct shipments of these lots from Sandoz have been sent a recall notification packet.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>NDC (24-count)</th>
<th>Lot Number</th>
<th>Expiration Date</th>
<th>Manufacturer</th>
<th>Distributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transderm Scop® (Scopolamine) TDS, 1.5mg (NDC 10019-553-88)</td>
<td>10019-553-02</td>
<td>FV5908</td>
<td>06/2018</td>
<td>ALZA (Vacaville, CA)</td>
<td>Baxter for Sandoz Inc./GlaxoSmithKline</td>
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<td>GF6017</td>
<td>01/2019</td>
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<td></td>
<td>GH8065</td>
<td>02/2019</td>
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Our records indicate that you received shipments of these lots between December 2015 and July 2016. Therefore, please examine your inventory immediately to determine if you have any quantities of these lots.

We ask for your cooperation in taking the following actions:

1. **Immediately stop distribution of these lots only and quarantine any quantities of these lots remaining in your control.**
2. If you have further distributed these lots, up to and including the Retail Level, then please contact these accounts immediately, advise them of the recall and have them return their outstanding recalled stock to you for return. Please advise your accounts that this recall is to the Retail Level.
3. **Conduct a physical count and record this data on the included Business Reply Form and the Packing Slip.**
4. **Mail the postage paid Business Reply Form even if you do not have the recalled product in your inventory.**
5. Return the recalled product and the Packing Slip using the prepaid FedEx Return Service shipping label to the address below:

   **GENCO Pharmaceutical Services**
   
   **6101 North 64th Street**
   
   **Milwaukee, WI 53218**

Do not include non-Sandoz items or other Sandoz labeled items in your shipment. All product not associated with this recall will be destroyed and no credit issued. Please report any adverse reactions by calling Sandoz at (800) 525-8747 or by emailing Sandoz at http://www.sandoz.com/legal/report_adverse_event_report.shtml. 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. For product or reimbursement questions regarding the lot listed above, please call Sandoz at (800) 525-8747. For questions about the recall process, please call GENCO Pharmaceutical Services at 877-319-8960 between the hours of 7:00 AM to 5:00 PM Monday - Friday (CST). If you have any other questions, please contact your Manager of National Accounts.

We appreciate your immediate attention and cooperation and apologize for any inconvenience caused by this action.

Sincerely,

Brian Bird, Executive Director, External Supply Quality Operations