**\*\*URGENT\*\***

 ***Drug Recall***

1825 NW Vivion Road December 9, 2021

## Riverside MO 64150

Dear Valued Customer:

**URGENT: Clindamycin and Benzoyl Peroxide gel 1%/5%**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description** | **NDC** | **Lot numbers** | **YES, I have product to return to Sedgwick** | **NO, I do not have product to return to Sedgwick** |
| Clindamycin/Benzoyl Perox 1%/5% Gel 25gm | 00781726368 | 11557C1, 11552B1, 12206A1 |  |  |

Tolmar Inc. is initiating a voluntary recall of the above lots of CLINDAMYCIN AND BENZOYL PEROXIDE GEL, distributed by Sandoz Inc. This recall has been initiated because stability testing has found lot 11557C1 to be Out of Specification (OOS) based upon Tolmar’s stability testing of the lot obtained at the 12-month timepoint for clindamycin phosphate in the reconstituted product. The adverse skin reaction would likely initially present as irritant contact dermatitis that would likely be noticeable by users prior to becoming a serious medical problem. As this is a topical product, the risk is considered low from a medical perspective.

The recall of the above referenced products is being conducted to the **RETAIL LEVEL** and is being conducted with the knowledge of the U.S. Food and Drug Administration. Please examine your inventory immediately and quarantine any affected product. **Contact Sedgwick at 888-216-6302** to obtain a recall kit, which will include a prepaid call tag. Once you receive the prepaid label, **return product to Sedgwick at:**

**Sedgwick Brand Protection**

**2670 Executive Drive**

**Indianapolis, Indiana 46241**

If you purchased this product from the PBA Health Distribution Center, please fill in the amount you have to return to Sedgwick and sign below. ***Please be sure to indicate your Customer ID or NCPDP to avoid multiple notifications***. The signed letter may be faxed to your PBA Health Pharmacy Customer Service Representative at 1-877-535-3803 or emailed to customerservice@pbahealth.com.

***\*\*\*RETURN THIS LETTER, WHETHER OR NOT YOU HAVE ANY AFFECTED PRODUCT ON HAND\*\*\****

Pharmacy Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Customer ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Thank you in advance for your cooperation.

Sincerely,

*The Recall Team at PBA HEALTH*